UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, *et al.*, *ex rel.* JESSICA PENELOW and CHRISTINE BRANCACCIO,	:	No. 12-cv-07758 (GC) (LHG)
Plaintiffs,	:	FINAL PRETRIAL ORDER
v.	:	
JANSSEN PRODUCTS, LP,	:	
Defendant.	:	

This matter having come before the Court for a pretrial conference pursuant to Fed. R. Civ. P. 16; and Sherrie R. Savett, Joy P. Clairmont, Michael T. Fantini, and William H. Ellerbe of Berger Montague PC and Joshua M. Russ and Andrew O. Wirmani of Reese Marketos LLP, and Peter S. Pearlman of Cohn Lifland Pearlman Herrmann & Knopf LLP, having appeared for Relators Jessica Penelow and Christine Brancaccio ("Relators"), and Abigail Hazlett, Brian M. Nichilo, and Michael A. Schwartz of Troutman Pepper Hamilton Sanders LLP and Allison M. Brown and Geoffrey M. Wyatt of Skadden, Arps, Slate, Meagher & Flom LLP having appeared for Defendant Janssen Products, LP ("Janssen"); the following Final Pretrial Order is hereby entered:

1. **JURISDICTION** (set forth specifically). Jurisdiction is founded upon the Federal False Claims Act, 31 U.S.C. § 3729 *et seq*., specifically 31 U.S.C. § 3732(a) and (b), and also 28 U.S.C. §§ 1331 and 1345.

2. **PENDING/CONTEMPLATED MOTIONS** (Set forth all pending or contemplated motions, whether dispositive or addressed to discovery or to the calendar. Also, set forth the nature of the motion and the return date. If the Court indicated that it would rule on any matter at pretrial, summarize that matter and each party's position).[1]

[1] The parties have met and conferred, and will continue to meet and confer, regarding these contemplated motions and believe they may be able to stipulate to the exclusion of particular topics. When the parties file their pretrial

Relators' Contemplated Motions

1. Motion to exclude any reference to Relators' retention or fee agreement with Relators' counsel. (True MIL).
2. Motion to exclude any argument that Relators were not injured by Janssen's conduct. (True MIL).
3. Motion to preclude Janssen from taking any trial depositions at this juncture of the case, and from presenting any witness through a trial deposition or by remote means. (True MIL).
4. Motion to exclude Janssen from introducing evidence that Prezista or Intelence saved lives or about the devastating effects of HIV/AIDS. (True MIL).
5. Motion to exclude arguments regarding public policy regarding HIV drugs and accessibility to patients. (True MIL).
6. Motion to exclude arguments regarding Janssen's and/or Johnson & Johnson's good character or good reputation. (True MIL).
7. Motion to exclude any reference to Janssen's or Johnson & Johnson's other drugs, such as Covid vaccines, and their service of the public good. (True MIL).
8. Motion to exclude reference to any potential adverse impact a damage award would have on Janssen or the pharmaceutical industry. (True MIL).
9. Motion to exclude reference to treble damages, civil penalties, and attorneys' fees, expenses, and costs. (True MIL).
10. Motion to exclude reference to the United States' and the Plaintiff States' decisions to decline to intervene in the case and their non-participation at trial. (True MIL).
11. Motion to exclude Dr. Jena's opinions on causation and damages as contrary to the law. (True MIL).
12. Motion to exclude Janssen's benefit of the bargain defense regarding damages as contrary to the law. (True MIL).
13. Motion to exclude reference to other pharmaceutical companies' use or implementation of speaker programs, including but not limited to the purpose of the programs, or amounts paid to speakers. (True MIL).
14. Motion to exclude all pleadings as evidence. (True MIL).
15. Motion to allow Relators to call a Janssen corporate representative to testify on substantive issues, and to authenticate Janssen documents. To be briefed at trial or in trial brief

motions, they intend to file a joint stipulation of agreed-to in limine topics that do not require briefing.

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16. Motion to preclude Janssen from introducing any document that it did not produce in discovery. (True MIL).

17. Motion to exclude any evidence relating to any performance reviews, performance evaluations, performance and/or written warnings, performance and development plans and corrective action plans as irrelevant, unfairly prejudicial and inadmissible under Rules 403 and 404. (True MIL).

Janssen's Contemplated Motions

1. Motion in limine to preclude Relators and certain lay witnesses from testifying on why doctors were selected to be speakers for Janssen, whether the doctors were qualified to speak, and Janssen's purpose or intent in paying these doctors for their professional services, based on lack of personal knowledge. — True MIL

2. Motion in limine to preclude Relators and certain lay witnesses from providing inadmissible lay opinion testimony on the effect of Janssen's promotion on doctors' prescribing decisions. — True MIL

3. Motion to exclude any evidence or argument referencing other investigations, litigation, or settlements (including, but not limited to, corporate integrity agreements) involving Janssen or any other pharmaceutical company (including, but not limited to, Johnson & Johnson or any of its subsidiaries) and the federal government as irrelevant, unfairly prejudicial, and otherwise inadmissible propensity evidence under Rule 404(b). — True MIL

4. Motion to exclude any evidence or argument referring to Janssen's promotion of Prezista's lipid profile, Prezista prescriptions written for patients with lipid conditions, or claims submitted for Prezista prescriptions written for patients with lipid conditions as "off-label." — True MIL

5. Motion to exclude any evidence referring to Prezista or Intelence prescriptions as "misbranded" or otherwise "illegal." — True MIL

6. Motion to exclude any evidence or argument referencing regulatory or other government guidance (including, but not limited to, guidance gleaned from corporate integrity agreements) on speaker programs or other promotional activities after 2014 as irrelevant and unfairly prejudicial. — True MIL

7. Motion to exclude any evidence or argument regarding the amount of funds Janssen may have set aside to litigate the case as irrelevant and unfairly prejudicial. — True MIL

8. Motion to exclude any evidence or argument referencing Anthony Dolisi's assertion of his Fifth Amendment right to refuse to answer questions in response to a Civil Investigation Demand for Oral Testimony. — True MIL

9. Motion to compel the testimony of Dr. H. Clifford Lane (Deputy Director for Clinical Research and Special Projects, National Institutes of Allergy and Infectious Diseases, — Motion to be filed by 11/10/22; opposition due 11/21/22; reply due 11/28/22; returnable 12/5/22

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National Institutes of Health) and B. Kaye Hayes (Executive Director and Designated Federal Officer for the Presidential Advisory Council on HIV/AIDS).[2]

3. **STIPULATION OF FACTS** (Set forth in narrative form a comprehensive listing of all uncontested facts, including all answers to interrogatories and admissions, to which there is agreement among the parties).

I. The Parties

1. Defendant Janssen Products, LP ("Janssen") is a subsidiary of Johnson & Johnson and is incorporated in New Jersey.

2. Throughout the relevant time period of 2006 through 2014 (the "Relevant Time Period"), Janssen manufactured, marketed, and promoted Prezista.

3. Throughout the period of 2008 through 2014, Janssen manufactured, marketed, and promoted Intelence.

4. Tibotec Therapeutics ("Tibotec") was previously a subsidiary of Johnson & Johnson and changed its name in 2011 to Janssen Therapeutics, a division of Janssen.

5. Jessica Penelow and Christine Brancaccio are Plaintiff-Relators ("Relators") in this action. Relators bring this action on behalf of the United States, twenty-six states, and the District of Columbia.

6. The United States is one of the real parties of interest in this action.

7. The United States' Department of Health and Human Services ("HHS") and the Centers for Medicare and Medicaid Services ("CMS") administer the Medicare and Medicaid Programs.

8. In addition, the District of Columbia and the following states (collectively, the "Plaintiff States") are the other real parties of interest in this action: California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, and Washington. Throughout the Relevant Time Period, Prezista and Intelence were provided to Medicaid beneficiaries in the Plaintiff States and were paid for by the Plaintiff States' Medicaid Programs using a combination of the Plaintiff State's funds and federal funds.

9. From the start of the relevant time period in 2006 through 2013, Ms. Penelow worked as a Senior Virology Sales Specialist at Janssen (formerly Tibotec) and was responsible for

[2] In May 2022, counsel for Janssen served subpoenas seeking Ms. Hayes's and Dr. Lane's testimony at trial. These subpoenas were properly served in accordance with *U.S. ex rel. Touhy v. Ragen*, 240 U.S. 462 (1951), and all applicable statutes and regulations. Counsel for Janssen has been in contact with counsel for Ms. Hayes, counsel for Dr. Lane, and the assigned Assistant United States Attorney from the District of New Jersey, and are awaiting further responses from them. At this time, Janssen believes that it may become necessary to move to compel Ms. Hayes's and Dr. Lane's testimony.

selling and marketing Prezista and Intelence to doctors[3] on the Lower East Side of Manhattan, New York.

10. Throughout the Relevant Time Period, Ms. Brancaccio worked as a Virology Sales Specialist at Janssen (formerly Tibotec) and was responsible for selling and marketing Prezista and Intelence to doctors in Queens and Long Island, New York.

II. Prezista and Intelence

11. Prezista and Intelence are two antiretroviral drugs ("ARVs") developed to treat patients infected with HIV/AIDS.

12. Prezista was approved for use by treatment-naïve patients on October 21, 2008.

13. Intelence was approved by the FDA on January 18, 2008.

III. Prezista and Intelence Compared to Other Anti-Retroviral Drugs

14. Prezista is in the class of protease inhibitors ("PI") ARVs.

15. The other nine PI ARVs are:

    a. Invirase (squinavir), approved on 12/6/1995.

    b. Norvir (ritonavir), approved on 3/1/1996.

    c. Indinavir (crixivan) approved on 3/13/1996.

    d. Viracept (nelfinavir), approved on 3/14/1997.

    e. Agenerase (amprenavir), approved on 4/15/1999.

    f. Kaletra (lopinavir), approved on 9/15/2000.

    g. Reyataz (atazanavir), approved on 6/20/2003.

    h. Lexiva (fosamprenavir), approved 10/20/2003.

    i. Aptivus (tipranavir), approved 6/22/2006.

16. Intelence is in the class of non-nucleoside reverse transcriptase inhibitors (NNRTIs).

17. The other six NNRTIs are:

    a. Viramune (nevirapine), approved 6/21/1996.

    b. Rescriptor (delavirdine), approved 4/4/1997.

    c. Sustiva (efavirenz), approved 4/17/1998.

[3] "Doctors" as referred to herein is defined to encompass Medical Doctors as well as other health care providers, including but not limited to Nurse Practitioners, Physicians' Assistance, and Doctors of Pharmacy.

d. Atripla (efavirenz/emtricitabine/tenofovir), approved 7/12/2006.

e. Edurant (rilpivirine), approved 5/20/2011.

f. Complera (emtricitabine/rilpivirine/tenofovir), approved 8/10/2011.

IV. Janssen's Marketing and Promotion of Prezista and Intelence

18. Janssen promoted and marketed Prezista and Intelence to doctors through sales calls and through promotional speaker programs.

V. HHS Guidelines

19. The Department of Health & Human Services ("HHS") publishes consensus-based HIV treatment guidelines (the "HHS guidelines").

20. The HHS guidelines are generally updated multiple times each year to incorporate, among other things, peer-reviewed journals and data presented at major conferences.

4. RELATORS' CONTESTED FACTS (State separately for each plaintiff. Proofs shall be limited at trial to the matters set forth below. Failure to set forth any matter shall be deemed a waiver thereof).

A. Relators intend to prove the following contested facts with regard to liability:

The Relevant Government Health Care Programs

a. Medicare

1. Medicare Part D provides prescription drug coverage for the elderly and people with certain disabilities.

2. Under Medicare Part D, the federal Government helps to cover the costs of "covered Part D drugs," which are FDA-approved medications prescribed for a "medically accepted indication." 42 U.S.C. § 1395w-102(e)(1).

3. Under Medicare Part D, the federal Government does not reimburse for claims that are not for a medically accepted indication and/or not reasonable and necessary. 42 U.S.C. §§ 1395w-102(e)(1), (e)(3); 42 U.S.C. § 1395y(a)(l)(A); 42 U.S.C. § 1396r-8(d)(1)(B)(i); 42 C.F.R. § 411.15(k)(1); and 42 C.F.R. § 423.505(i)(4)(iv).

b. Medicaid

4. Medicaid provides healthcare coverage for low-income people.

5. Medicaid is funded jointly by the federal Government and states, with the federal Government contributing approximately 50% to 83% of the funding, and states contributing the rest.

6. The federal Government's share of a state's Medicaid expenditures is called federal financial participation ("FFP").

7. Although the federal Government oversees Medicaid, the program is administered on a state-by-state basis, and states have discretion to customize their plans.

8. A prescribed drug covered by a state Medicaid plan is eligible for FFP. CMS, Medicaid Drug Rebate Program Notice for State Technical Contracts, at 4 (Oct 5. 2016); *see also* 42 C.F.R. § 441.25.

c. ADAP

9. States create and administer their own AIDS Drug Assistance Programs ("ADAPs") through federal block grants that fund "core medical services" for HIV patients, including paying for HIV medications. 42 U.S.C. §§ 300ff-22(a)(1), (b)(3)(B).

10. The purpose of the ADAPs is to ensure that low-income HIV patients who do not qualify for Medicare, Medicaid, or private insurance—or whose health insurance provides insufficient coverage—have access to their prescribed HIV medications.

The Relevant Drugs -- Prezista and Intelence

11. Drugs used to treat patients infected with HIV/AIDS, antiretrovirals (ARVs), have been developed through funding and research from Government agencies, non-profits, research universities, and pharmaceutical companies.

12. Prezista (darunavir) was developed by Dr. Arun Ghosh of the University of Illinois Chicago and other scientists from the NIH in the 1990s.

13. Tibotec Pharmaceuticals, Ltd. licensed Prezista from the NIH in July of 2001.

14. Johnson & Johnson acquired Tibotec for $320 million on April 18, 2002.

15. Prezista was initially approved by the Food and Drug Administration in 2006 only for treatment-experienced patients, who are currently taking or have previously taken ARV drugs.

16. Prezista's initial approval was based on only 24-weeks of safety and efficacy data.

17. When Prezista launched, the patent exclusivity period for Prezista was scheduled to end in 2015.

18. Prezista's FDA-approved label eliminated all newly diagnosed HIV patients from the potential market for the drug and limited its use to only patients who needed to be switched from another drug.

19. Prezista's initial label listed hypercholesterolemia and hyperlipidemia as Adverse Reactions, and those Adverse Reactions were present in every version of the label in effect from June 23, 2006 through October 20, 2008.

20. Every iteration of Prezista's label approved on or after October 21, 2008 through the end of 2014 contained the Adverse Drug Reactions of hypercholesterolemia, hypertriglyceridemia, and increased low density lipoprotein.

21. Intelence was approved in 2008 based on only 24 weeks of safety and efficacy data.

22. For Intelence, Janssen never supplemented the 24 weeks of safety and efficacy data that it used to gain the FDA's original approval for Intelence in 2008.

23. Intelence was only approved for a subgroup of treatment-experienced patients (*i.e.*, those with "viral strains resistant to an NNRTI and other [ARV] agents"), and its approved label required that it be taken twice-a-day.

Prezista and Intelence Compared to Other Anti-Retroviral Drugs

24. From the period of 1987-2014, the FDA approved at least 35 ARVs for treatment for patients infected with HIV/AIDS, two of which were Prezista and Intelence.

25. The FDA has not approved any new protease inhibitors since it approved Prezista on June 23, 2006. Thus, at the time of Prezista's approval, there were nine other approved PIs on the market (and there have not been any approved since Prezista).

26. Eight other PIs could be prescribed for treatment naïve patients, five could be dosed once-a-day, one did not have warnings about lipid side effects in its label (Reyataz), and eight had safety data of at least 48 weeks.

27. The label of Reyataz, a drug in the PI class like Prezista, did not require that it be co-administered with the drug ritonavir, which also increased lipids. The label for Prezista always required that it be co-administered with ritonavir.

28. Prezista was the third most expensive PI in terms of the average amount the federal Government reimbursed for prescriptions ($30.36/day for each patient on the drug) in the Relevant Time Period.

29. At the time Intelence was approved, there were four other approved NNRTIs on the market. All could be prescribed for treatment naïve patients, and three out of four could be dosed once daily. Intelence only ever had 24 weeks of safety data in its label, while all the other NNRTIs had at least 52 weeks of safety data in their labels.

30. Intelence was the most expensive NNRTI ($25.55/day for each patient) in terms of the average amount reimbursed by the federal Government during the Relevant Time Period except for Atripla, which was a combination of three drugs.

31. In addition to the ARVs listed above, the other ARVs approved by the FDA in the period of 1987-2014 include:

    a. Retrovir, approved 11/19/1987.

    b. Videx, approved 10/9/1991.

    c. Zerit, approved 6/24/1994.

    d. Epivir, approved 11/17/1995.

    e. Combivir, approved 9/26/1997.

    f. Ziagen, approved 12/17/1998.

    g. Trizivir, approved 11/14/2000.

h. Viread, approved 10/26/2001.

i. Emtriva, approved 7/2/2003.

j. Epzicom, approved 8/2/2004.

k. Truvada, approved 8/2/2004.

l. Stribild, approved 8/27/2012.

m. Tivicay, approved 8/13/2013.

n. Triumeq, approved 8/22/2014.

o. Tybost, approved 9/24/2014.

32. After Indinavir was approved in 1996, the only two drugs approved by the FDA using Phase II trial registrational studies with only 24 weeks of patient safety data (as opposed to Phase III trial registrational studies with at least 48 weeks of patient safety data) were Prezista and Intelence.

33. The following ARVs (including all classes) approved by the FDA did not have any warning about lipid-related conditions as reactions or adverse events in their labels in the period of 2006-2014: Retrovir, Videx, Zerit, Epivir, Viramune, Combivir, Reyataz, Selzentry, and Isentress.

34. In addition to Prezista, the following ARVs (including all classes) were approved by the FDA for use in treatment naïve patients at some point in the 2006-2014 time period: Retrovir, Videx, Zerit, Epivir, Invirase, Norvir, Viramune, Crixivan, Viracept, Rescriptor, Combivir, Sustiva, Ziagen, Agenerase, Kaletra, Trizivir, Viread, Reyataz, Emtriva, Lexiva, Epzicom, Truvada, Atripla, Edurant, Complera, Stribild, Tivicay, Triumeq, and Tybost.

35. In addition to Prezista, the following ARVs (including all classes) were approved by the FDA for once-daily dosing in at least some patient populations: Videx, Epivir, Viramune, Crixivan, Sustiva, Ziagen, Agenerase, Kaletra, Viread, Reyataz, Emtriva, Lexiva, Epzicom, Truvada, Atripla, Edurant, Complera, Stribild, Tivicay, Triumeq, and Tybost.

Janssen's Marketing and Promotion of Prezista and Intelence

36. Janssen purposely targeted about 5,200 doctors for its sales calls and marketing, and these providers wrote 80% of the prescriptions for Prezista and Intelence.

37. Also, as Janssen knew from its own documents, about 70% of the claims submitted for Prezista and Intelence were paid by Government payors such as Medicare, Medicaid, and ADAP.

38. Prezista was the first HIV drug that Janssen had ever marketed and sold.

39. Soon after Prezista's launch in June 2006, Janssen's sales were far below its sales forecasts.

40. In July 2006, Janssen had only sold 896 prescriptions of Prezista as compared to forecasts of 3,700, meaning that actual sales were less than 25% of the company's forecasts.

41. Janssen established sales goals for each of its sales representatives specifying how many prescriptions of its drugs it expected the doctors in the representatives' territory to prescribe in a given time period.

42. If the sales representatives met or exceeded their sales goals, they were rewarded with bonuses, which were given quarterly and which could amount to up to 20% of their base pay.

43. Emails tracking the sales performance of Prezista and Intelence were regularly circulated among senior Janssen managers and executives, including the current Vice Chairman of Johnson & Johnson's Executive Committee, Joaquin Duato.

44. As approved, Prezista and Intelence had limited indications, side effects, or dosing that limited their marketability.

45. Janssen's senior executives held many meetings and phone calls with sales representatives where they discussed how to increase sales of the drugs.

46. Even before the launch of Prezista, Janssen had identified that it would need to use an off-label ("OL") DART Study to favorably differentiate Prezista's effect on lipids from competitor drugs, Reyataz and Kaletra.

47. Janssen marketed Prezista as being "lipid friendly," having a "lipid neutral" profile, and/or as being "lipid neutral or friendly like Reyataz" through its sales representatives who made sales calls on individual doctors and through the doctors Janssen paid as speakers. As a result, Janssen misbranded Prezista.

48. Prescriptions for Prezista resulting from Janssen's false and misleading statements about Prezista's lipid profile were not reasonable and necessary for the treatment of patients who had concerning levels of lipids, triglycerides, and/or cholesterol and/or had already been prescribed a statin or other drug to address lipids, triglycerides, and/or cholesterol.

49. Subject to individual patient resistance or other issues, it would have been medically inappropriate to prescribe Prezista to a patient who already suffered from or was at high risk of a lipid-related problem, which would include, but not be limited to, any patients who were taking any lipid-lowering drugs or who had a lipid-related diagnosis prior to the first time they were prescribed Prezista.

50. Janssen's marketing of Prezista as "lipid friendly," having a "lipid neutral" profile, or as being "lipid neutral or friendly like Reyataz" caused or would have been a substantial factor in the doctor's willingness to prescribe Prezista for a patient with lipid-related problems. Janssen's unlawful marketing interfered with and corrupted doctors' medical judgment and detrimentally impacted HIV/AIDS patients.

51. Prezista's lipid profile placed it at a competitive disadvantage to Reyataz, which was a competitor's HIV drug on the market at the same time, and which did not cause an

increase in cholesterol.

52. Marketing Prezista as being "lipid friendly," having a "lipid neutral" profile, or as being "lipid neutral or friendly like Reyataz" caused Prezista to be misbranded.

53. Janssen illegally marketed Prezista through its sales representatives who made sales calls on individual doctors and through the doctors Janssen paid as speakers as being suitable for treatment naïve patients before October 21, 2008, when its label was expanded.

54. Janssen's marketing message that Prezista could be used in patients other than those identified in its label—namely, treatment-experienced adult HIV patients, such as patients with HIV-1 strains resistant to more than one protease inhibitor—was misleading and not an approved indication under Prezista's FDA label prior to October 21, 2008.

55. Janssen's marketing of Prezista as being appropriate for use in treatment naïve patients before October 21, 2008 caused or would have been a substantial factor in the doctor's willingness to prescribe Prezista for a treatment naïve patient. Janssen's unlawful marketing interfered with and corrupted doctors' medical judgment and detrimentally impacted HIV/AIDS patients.

56. Marketing Prezista as being appropriate for treatment naïve patients in the period before October 21, 2008 caused Prezista to be misbranded.

57. In July 2006, just weeks after Prezista's launch, Janssen's President Glenn Mattes, along with Mike Iacobellis, the National Sales Director, and other managers, decided that Janssen needed to promote Prezista for off-label indications in order to expand its market size, sales, and profitability.

58. Janssen senior executives Glenn Mattes, Mark Gossett, and Mike Iacobellis ordered, trained, and bonused employees throughout the company, down to the sales representatives, to engage in off-label or inappropriate promotions of Prezista.

59. Two years later, when Intelence was launched in 2008 with limits on its approved uses, these same executives (Mattes, Gossett, and Iacobellis) directed Janssen employees to market Intelence to doctors for off-label indications in order to expand its market size and boost its sales and profitability.

60. Janssen illegally marketed Intelence as being safe and effective when taken once-a-day ("QD") through its sales representatives who made sales calls on individual doctors and through the doctors Janssen paid as speakers.

61. Janssen illegally marketed Intelence as being safe and effective when taken once a day by directing its sales representatives to refer to and disseminate copies of the off-label study "Pharmacokinetics of Once-Daily Etravirine (ETR) Without and With Once-Daily Darunavir/Ritonavir (DVR/r) in Antiretroviral-Naive HIV-1 Infected Adults," DeJesus et al., Antiretroviral-Naïve HIV-1 Infected Adults, Antiviral Therapy, 2010 15:711-720, doi:10.385/IMP1562 (the "DeJesus Study").

62. Dosing Intelence once-daily is not supported by the weight of medically accepted

standards for HIV/AIDS treatment.

63. Janssen's marketing message that Intelence could be dosed QD safely and effectively was misleading and illegal. It directly contradicted the FDA-approved label which provided for twice-a-day dosing.

64. Janssen's marketing message that Intelence could be dosed QD safely and effectively caused or would have been a substantial factor in the doctor's willingness to prescribe Intelence QD. Janssen's unlawful marketing interfered with and corrupted doctors' medical judgment and detrimentally impacted HIV/AIDS patients.

65. Dosing Intelence once-daily poses serious concerns for patient harm because the drug may not be effective for the full 24 hours between doses; because the dose that remains in the patient's body at the end of the 24 hour period may not be sufficiently strong to suppress the HIV virus on the patient; and because if the patient missed a dose, they would be without the required dosage for an even longer period of time.

66. Intelence's twice-a-day dosing placed it at a competitive disadvantage in the marketplace because prescribing doctors and HIV patients generally prefer a simpler medication regimen (*i.e.*, ARVs that can be taken once a day).

67. Marketing Intelence as being appropriate for QD dosing caused Intelence to be misbranded.

68. Janssen illegally marketed Intelence as being safe and effective for treatment naïve patients through its sales representatives who made sales calls on individual doctors and through the doctors Janssen paid as speakers.

69. Janssen's marketing message that Intelence could be used in patients other than treatment-experienced adult patients who also have evidence of viral replication and HIV-1 strains resistant to an NNRTI and other antiretroviral agents was misleading and not an approved indication under Intelence's FDA label.

70. Janssen's marketing message that Intelence could be prescribed for treatment naïve patients caused or would have been a substantial factor in the doctor's willingness to prescribe Intelence QD. Janssen's unlawful marketing interfered with and corrupted doctors' medical judgment and detrimentally impacted HIV/AIDS patients.

71. Marketing Intelence as being appropriate for treatment naïve patients caused Intelence to be misbranded. It directly contradicted the FDA label which indicated Intelence could only be marketed for treatment experienced adult patients who also have evidence of viral replication and HIV-1 strains resistant to an NNRTI and other antiretroviral agents.

72. Sales representatives across the country delivered the off-label messages about Prezista and Intelence throughout the 2006-2014 time period.

73. Janssen executives directed that Key Account Managers ("KAMs"), District Managers, and sales representatives be trained and/or instructed to promote: **(**a) Prezista as being suitable for treatment-naïve patients (a patient population that it was not approved for until October 21, 2008); (b) Prezista as "lipid neutral," "lipid friendly," or "lipid neutral or friendly just like Reyataz" (a competitor drug), contrary to Prezista's FDA-approved

label; (c) Intelence as being safe and suitable for treatment-naïve patients (a patient population it was not approved for); and (d) Intelence as being suitable for once-a-day dosing, contrary to its label requiring twice-a-day dosing.

74. Intelence was inferior to protease-inhibitor-based regimens for treatment naïve patients, and it should have been reserved as a treatment option for patients who were both NNRTI-experienced and PI-experienced.

75. At the direction of upper management, Donna Graham, National Sales Trainer from 2007 to 2009, trained the sales representatives to engage in OL promotion of the drugs.

76. If sales representatives did not meet their sales goals, they were denied bonuses, placed on performance reviews, and even fired.

77. It was difficult or impossible for sales representatives to meet their sales targets without OL marketing, such that representatives who refused to engage in OL marketing were denied bonuses or forced out of the company.

78. Janssen closely monitored each sales representative's sales, and each prescribing doctor's prescriptions, of Prezista and Intelence.

79. In some cases, the tracking reports Janssen used showed explicit off-label sales figures. For example, Janssen's Monthly Performance Report dated January 28, 2008 states that "Prezista naïve share grew to 7% by 2007 year end," despite the fact that Prezista was not approved for treatment-naïve patients in 2007.

80. If a doctor was prescribing a competitor's HIV drug, or his/her prescriptions of Prezista and Intelence were low, Janssen would target that doctor for more sales calls during which the sales representatives would provide more off-label information in order to boost the doctor's prescriptions.

81. Janssen would then look at the prescription reports to see if the off-label messaging was effective.

82. Janssen's District Managers, who often accompanied sales representatives on their sales calls to see how they were marketing the drugs to doctors, would coach sales representatives on how to deliver the off-label messages, and would even deliver the off-label messages themselves to doctors on the sales calls.

83. Janssen sales representatives followed Janssen's directives and engaged in OL marketing of the drugs in order to increase their sales and meet their sales targets.

84. Janssen also provided sales representatives with OL studies to use on sales calls.

85. Janssen discussed and provided copies of studies concerning Prezista and Intelence to its sales representatives, including, but not limited to, the following:

    a. The "DART Study": Tomaka F, Lefebvre E, Sekar V. Similar changes in metabolic parameters of darunavir (TMC114) and atazanavir, each coadministered with low-dose ritonavir in healthy volunteers (TMC114-C159). In: American Conference for the Treatment of HIV (ACTHIV), Dallas, TX, 31 May–3 June 2007;

b. The "Metabolik Study": Aberg, et al., Metabolic Evaluation in Treatment-Naives Assessing the Impact of Two Boosted Protease Inhibitors on Lipids and Other Markers): Comparison of the Metabolic Effects of Darunavir/ritonavir [Prezista/Norvir] versus Atazanavir/ritonavir [Reyataz] over 12 weeks, AIDS Res Hum Retroviruses, 2012 Oct 28(10): 1184-1195; and

c. The "DeJesus Study" (also called the "Glasgow Study"): "Pharmacokinetics of Once-Daily Etravirine (ETR) Without and With Once-Daily Darunavir/Ritonavir (DVR/r) in Antiretroviral-Naive HIV-1 Infected Adults," DeJesus et al., Antiretroviral-Naïve HIV-1 Infected Adults, Antiviral Therapy, 2010 15:711-720, , doi:10.385/IMP1562.

86. The Dart Study, the Metabolik Study, and the DeJesus Study were not part of approved labels for Prezista and Intelence and were directly contradicted by the drugs' respective labels.

87. These studies used small sample sizes: the DeJesus Study had 23 subjects, DART Study had 49 subjects, and Metabolik Study had 34 subjects.

88. The 49 patients enrolled in the DART Study were not infected with HIV.

89. The DART Study, the DeJesus Study (also called the Glasgow Study), and the Metabolik Study were discussed and provided to sales representatives to discuss with and improperly distribute to doctors on sales calls.

90. The DART Study, the DeJesus Study, and the Metabolik Study used sample sizes too small to be statistically relevant.

91. Another aspect of Janssen's unlawful scheme involved the use of Medical Information Request forms ("MIRs"), which are required to originate from the doctors.

92. Janssen improperly coached its sales representatives to prompt doctors to request off-label information about Prezista and Intelence via MIRs, with the belief that providing off-label information to doctors would cause them to increase their prescriptions.

93. Being under constant pressure to submit MIRs, sales representatives improperly prompted doctors to submit MIRs, often added a request for off-label information to an MIR form that a doctor had already signed, and even forged doctors' signatures on MIRs before submitting them to Janssen's Medical Affairs Department.

94. Janssen closely tracked the number of Medical Information Requests (MIRs) submitted by sales representatives. MIRs were used to provide doctors with information about the drugs, including off-label information.

95. In a weekly report from Mickey Allison to District Manager Tony Dolisi dated September 14, 2006, Allison wrote, under Company Tactics: "MIR forms are being widely used to get the 48-week data into the hands of all customers [doctors]."

96. Janssen employees purposely did not mention off-label topics in their written emails, reports, sales call database, or other writings because they knew that these Janssen practices were unlawful.

97. Janssen trained its employees and managers to avoid mentioning off-label topics and offering remuneration to doctors to induce or reward prescriptions in written emails, reports, sales call database entries, or other writings as part of its "Careful Communications" policy.

98. The market research surveys performed by vendors for Janssen called Awareness and Usage or "A&U" reports show: (a) Among Prezista's class of ARVs, lipid effect was an important consideration for prescribing doctors; (b) Over time, Janssen improved doctors' perceptions of Prezista's effect on lipids; (c) Being able to prescribe a drug once-a-day was a very important attribute; (d) Many of the doctors whom Janssen sales representatives called on and surveyed believed that Intelence could be dosed once-a-day; and (e) Some doctors reported recalling that Janssen sales representatives discussed the OL uses of Prezista and Intelence on their most recent sales call.

99. Janssen performed other surveys of doctors whom its sales representatives targeted showing that its sales representatives discussed OL uses of Prezista and Intelence with those doctors.

100. Other Janssen documents relating to sales forecasts that show that Janssen included future OL sales of its drugs into its sales forecasts; that Intelence and Prezista were being prescribed in the OL treatment-naïve markets; and that Janssen tracked these OL sales.

101. One of Janssen's off-label marketing schemes focused on patently false assertions that Prezista is "lipid neutral" or "lipid friendly" — that is, the drug purportedly would not affect or increase a patient's cholesterol and triglyceride levels — or claims that it was comparable to a competitor drug (Reyataz) in terms of lipids.

102. Janssen sales representatives routinely used the sales message that Prezista had the same lipid profile as Reyataz when they performed sales calls on doctors.

103. These false and misleading messages about the lipid effects of Prezista were delivered by speakers at most Speaker Programs, including the most highly compensated and most frequently appearing speakers, and were also elicited by Janssen-arranged "plants" in the audience.

104. Janssen contracted with a vendor to create marketing reports, which reflect that some of the most prominent marketing messages that sales representatives presented to doctors on sales calls included Prezista being touted as lipid neutral.

105. Janssen paid outside vendors millions of dollars to perform detailed marketing surveys of doctors who received sales calls from its representatives to determine what the doctors thought about Janssen's drugs and their competitors, what aspects of these drugs were most important to these doctors when making choices for their patients, and what marketing messages the doctors recalled receiving from the Janssen sales representatives.

106. Janssen also paid an outside company, Partners in Loyalty Marketing ("PILM"), to conduct return-on-investment analyses of certain HIV promotional initiatives.

107. Janssen tracked the off-label sales of these drugs, and included off-label sales in its sales forecasts.

108. Janssen paid millions of dollars to marketing consultants to provide ongoing feedback about the success of the company's marketing efforts, including the particular impact of the off-label promotional messaging. For instance, over the course of a single calendar year, Janssen paid ZS Associates $708,000 to perform surveys and create presentations of their findings, and it engaged that vendor on similar projects for several years (with at least 10 surveys having been completed by May 6, 2010).

109. As shown in Janssen's market research reports, including its Awareness and Usage reports, surveys of doctors revealed that some of the most prominent marketing messages they recalled hearing from Janssen sales representatives related to once-a-day dosing for Intelence, Intelence's use for treatment-naïve patients, and Prezista being touted as lipid neutral, all of which are off-label messages.

Janssen's Speaker Program

110. Janssen had a Speaker Program whereby it paid doctors to give speeches about Prezista and Intelence to other doctors.

111. The Speaker Program was primarily run by Janssen's Marketing Department.

112. Janssen paid 335 doctors to give 8,897 speeches during 2006 to 2014, which equates to 988 speeches per year, or more than three speeches per business day for nine years.

113. Janssen paid 48 doctors over $100,000 each and paid some doctors between $300,000 to $464,000.

114. The 48 doctors that Janssen paid $100,000 or more in honoraria for participation in the Speakers' Bureau were high prescribers of Prezista and/or Intelence, and they continued to prescribe the drugs. One purpose of these payments was to illegally induce doctors to prescribe Prezista and Intelence, or to illegally reward them for doing so.

115. Janssen paid for hotels, meals, and all travel expenses associated with attending speaker training sessions and delivering speeches. Janssen offered speaker positions with higher compensation, including travel expenses for speaker engagements that were designed to suit the speaker's personal travel needs, to doctors who were higher prescribers of Prezista and Intelence. One purpose of these payments was to illegally induce doctors to prescribe Prezista and Intelence, or to illegally reward them for doing so.

116. Janssen paid doctors approximately $1,000 to $3,000 for each speech, and it also paid them about $1,500 to attend annual training sessions.

117. For years up to 2011, Janssen capped the Speaker Program honoraria payments at $50,000 per speaker per year, which was increased to $75,000 per year in 2012. These caps did not include Janssen's payments to doctors for speaker travel expenses, Speaker Training fees, consulting fees, Advisory Board attendance fees, or meal costs.

118. Janssen also paid for hotels, meals, and all travel expenses associated with doctors attending speaker training sessions, speaking events, and advisory board meetings.

119. Janssen paid over $14 million to doctors just in speaker fees and millions of dollars overall on its Speaker Program. From 2010-2014 alone, Janssen spent more than $4.2 million on speaker travel expenses and food, drinks, and alcohol at speaker events.

120. Janssen increased its overall spending on the Speaker Program from year to year.

121. Speakers continued to prescribe Prezista and Intelence once they started giving paid speeches.

122. Janssen regularly tracked and analyzed prescription data relating to all doctors who prescribed Prezista and/or Intelence nationwide, including speakers.

123. One of the criteria that Janssen used to select doctors to be paid speakers was their prescription volume of Prezista or Intelence.

124. Speakers were more likely to prescribe Prezista and Intelence than non-speakers.

125. Speakers on average prescribed Prezista and Intelence at a higher rate than non-speakers.

126. Speakers, who were a relatively small share of all prescribers, tended to be high prescribers of Prezista and Intelence, and accounted for a disproportionate share of all Prezista and Intelence reimbursements.

127. Speakers accounted for a higher percentage of off-label Prezista and Intelence prescriptions than non-speakers.

128. In reports prepared by Janssen's marketing department, there were slides tracking the sales of the top prescribers of Prezista and Intelence in the country, many of whom were speakers for Janssen, including Joseph Gathe, Roberto Ortiz, Peter Ruane, Clayton Barbour, Nicholaos Bellos, Shannon Schrader, Jesse Sanders, Michael Dunn, Michael Mullen, Andre Brutus, Edwin Dejesus, Felix Carpio-Cedraro, Timothy Kanter, Thanes Vanig, and Jihad Slim.

129. In some cases, if Janssen could not track prescriptions by individual prescribers, it would track prescriptions associated with the institutions where those prescribers practiced as "key accounts."

130. Several of the key accounts were institutions where major speakers practiced, including Elizabeth Race, Lavesa Bhatti, Ralph Liporace, Ian McNicholl, Lauren Foster, Greg Huhn, Roger McAurther, Marian Rabe, Marah Lee, Jeffrey Lennox, Peter Shalit, Dushyantha Jayaweera, Luis Espinoza, Jihad Slim, Peter Alpert, Hilda Ortiz-Morales, Edwin DeJesus, Brad Hare, Monica Ghandi, Felipe Arias, and Antonio Urbina.

131. Sales of Prezista at these key accounts were presented on monthly performance reports for the marketing group so that Janssen could track sales of its drugs at those institutions.

132. Speeches were given to repeat attendees or a low number of attendees, as low as three people.

133. Hundreds of attendees attended the same speech multiple times, and some attended the

same speech over 60 times.

134. Paid speakers attended speeches given by other paid speakers.

135. These speaker-attendees include many of the highest-paid speakers (those receiving over $150,000 in honoraria), such as Michael Sension, Sorana Segal-Maurer, Bruce Rashbaum, Tim Kanter, and David Rubin.

136. Janssen sometimes selected the location of a speech relating to Prezista or Intelence based on its speaker's request to speak at a given location.

137. Janssen provided slide decks to speakers containing the substantive content to be delivered at speeches.

138. Janssen trained and coached speakers on how to deliver speeches.

139. Thousands of speeches were held in restaurants where food and alcohol were served.

140. In a recently issued HHS Special Fraud Alert, the Government noted that it had "significant concerns" about drug and device manufacturers paying speakers for speaker programs. The Special Fraud Alert urged companies to consider the "inherent" kickback risks associated with promotional speaker programs and advised them to consider "alternative less-risky means for conveying information."

141. Regulators, and even the pharmaceutical industry, are aware that paying doctors for promotional activities can be a disguise for kickbacks.

142. In the months before Prezista was approved for promotion by the FDA, in order to determine which doctors it would target to be speakers, Janssen analyzed the prescribing patterns and numbers of ARV prescriptions of the doctors in a given region, and prioritized for inclusion on Janssen's Speakers' Bureau the doctors who had the greatest potential to be prescribers of Janssen's drugs.

143. In the pre-launch period, Janssen compiled lists of doctors to target to become speakers made by its regional sales staff. This list explicitly stated that, in some cases, the reason the doctor was being targeted to become a speaker was that he or she was a "High Prescriber."

144. Janssen also identified doctors at key accounts (hospitals or clinics) as targets to become speakers to increase sales of its drugs from those accounts.

145. Janssen did not perform any legitimate "needs assessment" analysis to demonstrate that it had any real business need for more speakers and speeches while it continued to recruit more and more doctors to be paid speakers.

146. Janssen never performed an analysis of whether the speaker event attendees were learning anything from the events, or even changing their perceptions of Prezista and Intelence, as they did for their sales calls efforts.

147. Janssen tracked the prescriptions of Prezista and Intelence of its paid speakers and all speech attendees, and it also closely monitored the return on investment ("ROI") of its Speaker programs.

148. Janssen tracked prescription volume and dollar values of prescriptions written for all targeted doctors, which included speakers, and it monitored speakers' prescriptions before and after they gave speeches.

149. When calculating whether attendance at a speaker event increased an attendee's prescriptions of Prezista and Intelence, Janssen made no effort to exclude doctors who were both speakers and attendees from the calculation.

150. Many of Janssen's speakers also attended other speaker's events, and so their prescriptions were included in Janssen's ROI analysis.

151. Prescription volume was one of the most important criteria Janssen used to select speakers, and it was more important than the doctors' credentials.

152. Janssen employees told doctors that if they wanted to be added to the Speakers' Bureau or remain on it, they needed to prescribe the drugs, and if their prescriptions decreased, they would be removed.

153. Several doctors were removed from the Speakers' Bureau because their prescriptions were deemed insufficient, including Juan Bailey, Rita Kelly, and Linda Ording-Bauer.

154. Some doctors asked Janssen to be added to the Speakers' Bureau and said that if they were added, they would then prescribe the drugs.

155. Janssen also trained and coached speakers to present OL information at speeches, it provided speakers with "back up slides" that discussed the OL uses of the drugs, and it put "plants" in the audience to ask OL questions at speeches and prompt OL discussions.

156. OL messages were presented at most speaker presentations.

157. A speaker's willingness to incorporate impermissible OL discussions into the talks was also a significant factor that Janssen used in speaker selection and speaker retention, and Janssen coached its Key Account Managers on how to train the speakers to give off-label messages.

158. Janssen arranged for "plants" in the audience to ask off-label questions to prompt off-label discussions at speeches.

159. Off-label information about the drugs was regularly presented by the top paid speakers, such as Michael Sension and Elizabeth Race, and at many or most speeches.

160. The speeches delivered by Janssen speakers lasted about one hour each and were highly repetitive.

161. The slide decks used by Janssen speakers were used for multiple speeches, with little or no variation in content.

162. There was little or no educational value to the approved slideshow presentation for Janssen's speaker program.

163. The content of the approved speaker presentation slideshows for Prezista did not change materially throughout the 2006-2014 time period outside of the Prezista label expansion

in 2008.

164. The content of the approved speaker presentation slideshows for Intelence for the 2008-2014 time period did not change materially.

165. Many speeches were held at inappropriate venues; for instance, thousands of speeches (over 2,200) were given at high-end restaurants, including steak houses, where alcohol was served.

166. Despite the fact that PhRMA Code requires that meals provided to doctors at speaker events be modest by local standards, Janssen violated this requirement by holding events at extravagant venues like Pied a Terre in Miami Beach, Florida (four times the venue of a Janssen speaker events), which the Greater Miami Convention & Visitors Bureau describes as offering "a sensual dining experience on South Beach" that "awakens the taste buds and surprises the palate with innovative dishes created by chefs from 2- and 3- Michelin starred restaurants in France."

167. Janssen only provided data on the food costs-per-person of 5,482 events, but even among these, 1,917 events had costs in excess of $75 per person, and 158 events costs of $125 or more, even though Janssen's self-imposed limit for speaker events was $125.

168. The Janssen Compliance Department was not responsible for selecting speakers, determining the number of paid speakers or speeches, selecting attendees, limiting repeat attendance, selecting venues, controlling the costs of the events, or monitoring for OL promotion.

169. The operation of the Speaker Program was controlled by the Janssen Marketing Department and implemented by the sales representatives, who were incentivized to increase sales.

170. Janssen compliance personnel rarely attended speeches and had no legitimate means to assess whether OL information was discussed at speeches.

171. In a recently issued HHS Special Fraud Alert, the Government noted that it had "significant concerns" about drug and device manufacturers paying speakers for speaker programs. The Special Fraud Alert urged companies to consider the "inherent" kickback risks associated with promotional speaker programs and advised them to consider "alternative less-risky means for conveying information."

172. Many educational institutions, clinics, and hospitals (including those where some of Janssen's expert witnesses practice) prohibit their doctors or other employees from serving as paid speakers for drug companies.

173. Janssen used its Speaker Programs, including speaker trainings, and Advisory Board meetings as means to disseminate OL information to doctors who were speakers, consultants, and attendees, and to provide social entertainment to doctors.

174. Janssen's Speaker Programs, including speaker trainings, and Advisory Boards were shams in that they served no legitimate purpose and/or were designed to conceal kickbacks.

175. The Speakers' Bureau was a means for Janssen to make payments to speakers to illegally induce them to prescribe Prezista and Intelence, or to illegally reward them for doing so.

176. Janssen's underlying goal behind paying doctors to speak at the Speaker Programs, to attend speaker training sessions, and to participate as consultants in programs like Advisory Boards, was to have doctors maintain or increase their prescription volumes of Prezista and Intelence, including prescriptions that Janssen knew would be submitted and paid for in whole or in part by Government health care programs, including the health care programs of the federal Government and the Plaintiff States' Governments ("Government Health Care Programs").

Former Janssen Employees Who Have Provided Sworn Deposition Testimony

177. In addition to Relators' own knowledge and testimony, at least five other former employees provided substantial and corroborating testimony supporting Relators' Off-Label Marketing and Kickback Claims.

178. These five employees held different positions throughout Janssen (two at senior level positions), they worked in various geographic territories of Janssen, and they each independently testified to the same set of core facts establishing Janssen's liability. They had extensive oversight of, and/or interaction with, hundreds of employees throughout Janssen, and they personally participated in the conduct at issue here.

179. The employees are: (a) Mark Wilhelm, a Key Account Director for the West from 2007 to 2009, who oversaw eight Key Account Managers, about 70 sales representatives, and thousands of doctors' accounts spanning over 30 states, and who had direct involvement with Janssen's Speakers Bureau, including training and coaching about 100 speakers; (b) Sara Strand, a Regional Business Director for the East from 2006 to 2011, who oversaw about six District Managers, 70 sales representatives, and hundreds of doctors' accounts, and who had direct involvement in Janssen's Speakers Bureau; (c) Donna Graham, a National Sales Trainer from 2007 to 2009 and a sales representative from 2006 to 2007 and from 2009 to 2011, who personally trained all of the sales representatives and Key Account Managers across the U.S. on how to promote Prezista and Intelence to doctors on sales calls, and who also acted as a sales representative who promoted the drugs and had involvement in the Speakers Bureau; (d) Matthew Grooms, a sales representative in Missouri, Kansas, and Nebraska from 2006 to 2010, who personally promoted the drugs to doctors on sales calls, and who was involved with the Speakers Bureau; and (e) Joseph Holshoe, a sales representative in Rhode Island and Massachusetts from 2006 to 2009, who personally promoted the drugs to doctors on sales calls, and who was involved with the Speakers Bureau.

180. Former Janssen employees -- Donna Graham, Matthew Grooms, Joseph Holshoe, Sara Strand, and Mark Wilhelm -- are not plaintiffs in this case, have not been promised anything in exchange for their testimony, and have no financial interest in the outcome of the case.

181. Janssen never accused these employees of any acts of dishonesty, and they all left Janssen on their own volition.

Off-Label Marketing and Kickback Claims

182. Janssen knew that it was causing false claims to be submitted to Government Health Care Programs and false statements to be made to doctors because of its off-label marketing scheme, which included marketing off-label to doctors on sales calls and at speaker dinners, and its kickback scheme, because it had actual knowledge of the falsity of the claims and statements, it acted in deliberate ignorance of the truth or falsity of the claims and statements it caused, and/or it acted in reckless disregard of the truth or falsity of its claims and statements.

183. The claims and statements were false because they were ineligible for payment by Government Health Care Programs as they were for an off-label use or for a medically unreasonable or unnecessary use; were misbranded in violation of the Food, Drug and Cosmetics Act, 21 U.S.C. §§ 355(a) & (d); and/or contained false express certifications of compliance with the law, including the Anti-Kickback Statute.

184. The falsity of the claims that Janssen caused to be submitted to Government Health Care Programs as a result of its off-label marketing and kickback schemes was material to the Governments' decision to pay those claims.

185. Janssen's conduct was a substantial factor in causing false claims to be submitted to Government Health Care Programs, and the submission of false claims to Government Health Care Programs was foreseeable to Janssen and the normal consequence of Janssen's actions.

186. Janssen knowingly made or caused to be made false statements that were material to false or fraudulent claims through its off-label marketing and kickback schemes.

187. The false claims and statements that Janssen made or caused to be made were material to the Government Health Care Programs.

188. The FDA made it clear in its approval letters for Prezista and Intelence that the drugs must not be marketed for OL uses and failure to do so "may "render the product[s] misbranded."

189. The FDA's Division of Drug Marketing, Advertising & Communications (DDMAC) consistently and in multiple letters throughout the Relevant Time Period alerted Janssen that false and misleading messages about Prezista and Intelence, almost identical to those alleged in this case, were improper and should be remedied or immediately halted, including letters finding misleading: (a) materials regarding Prezista suggesting that it can be used in treatment naïve patients; (b) the use of a reprint of a clinical study that was not part of Prezista's approved labeling; (c) materials claiming Prezista has a low impact on cholesterol; (d) promotional materials regarding Intelence suggesting that it could be used in a broader patient population than the approved treatment experienced population.

190. Janssen's systematic OL promotion of these drugs caused or was a substantial factor in causing doctors to prescribe the drugs, and resulted in a substantial increase in their sales. The FDA made it clear in its approval letters for Prezista and Intelence that the drugs must not be marketed for OL uses and failure to do so "may "render the

product[s] misbranded."

191. Janssen knowingly and willfully offered or provided remuneration to doctors to induce or reward them for prescribing Prezista and Intelence, where payments for those drugs was reimbursed by Government Health Care Programs.

192. Janssen's payments to doctors for giving speeches and for other services such as the trainings and Advisory Board meetings were unlawful remuneration.

193. At least one of Janssen's purposes for offering remuneration to doctors as part of its Speaker Program, including speaker training, trips, meals, and Advisory Boards, was to induce the doctors to write more prescriptions for Prezista and Intelence, or to reward them for writing prescriptions of Prezista and Intelence.

194. Janssen caused pharmacies to submit false statements to Government Health Care Programs regarding their compliance with the Anti-Kickback Statute specifically, or with all "applicable" laws, when in fact prescriptions the pharmacies filled for Prezista and Intelence were not written in compliance with federal or state law.

195. All Janssen employees who directed, participated in, and carried out the off-label marketing scheme and kickback scheme acted under Janssen's direction and within the scope of their employment with Janssen.

196. Janssen knowingly caused false statements or misrepresentations of material facts to be made to permit payment under the Texas Medicaid program that is not authorized.

197. Janssen knowingly concealed or failed to disclose information to permit payment under the Texas Medicaid program that is not authorized.

198. Janssen knowingly caused claims to be presented to the Texas Medicaid program that contained statements or representations that Janssen knew or should have known to be false.

199. Janssen knowingly (meaning acted with knowledge or conscious indifference to the truth of the matter) offered to pay or give, or did pay or give, doctors gifts of money, a donation, or other items of value for the purpose of influencing the writing of prescriptions of Prezista and Intelence that would ultimately be paid for, in whole or in part, by the Texas Medicaid program.

Medicaid Provider Agreements

200. The Medicaid provider agreements from the Plaintiff States require providers to make certain certifications in order to participate in, and receive payments from, the State Medicaid Programs.

201. Some Medicaid provider agreements include language requiring providers like Janssen to expressly agree to request payment only for those services that are "medically necessary."

Government Information Regarding Off-Label Marketing

202. CMS has many resources specifically targeted to combatting illegal off-label promotion of drugs including: a. CMS Fact Sheet regarding (noting that if off-label promotion "causes Medicaid to be billed for pharmaceuticals used in this way, the people responsible for the promotion may be liable for false claims.") (Off-Label Pharmaceutical Marketing: How to Recognize and Report It (Oct. 2015), available at https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/off-label-marketing-factsheet.pdf, last accessed January 14, 2021; b. Podcasts (Cms.gov, Off-Label Use of Prescription Drugs, https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/podcast-Off-Label-Use-of-Prescription-Drugs-[March-2016].pdf, last accessed January 14, 2021; c. and CMS' Medicaid Program Integrity Education website (See https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Program/Education, last accessed January 14, 2021.)

203. Further, the Government has made multiple avenues available for observers to report off-label marketing, indicating the importance that the Government attaches to avoiding both the patient harm and the Government expense of such conduct.

204. There have also been numerous Congressional hearings addressing off-label marketing.

False Claims Act Case Settlements

205. There have been settlements in FCA cases related to off-label marketing, including settlements involving Janssen: a. Allergan agrees to plead guilty and paid $600 million to resolve allegations of off-label promotion of Botox, available at https://www.justice.gov/opa/pr/allergan-agrees-plead-guilty-and-pay-600-million-resolve-allegations-label-promotion-botox, last accessed January 14, 2021; b. Wyeth Pharmaceuticals agreed to pay $490.9 million for marketing the prescription drug Rapamune for unapproved uses, available at https://www.justice.gov/opa/pr/wyeth-pharmaceuticals-agrees-pay-4909-million-marketing-prescription-drug-rapamune-unapproved, last accessed January 14, 2021; c. Janssen and its parent company Johnson & Johnson reached settlements related to the off-label promotion of Risperdal for over $2.2 billion, available at https://www.justice.gov/opa/pr/johnson-johnson-pay-more-22-billion-resolve-criminal-and-civil-investigations, last accessed January 14, 2021; d. Janssen affiliate reached a settlement related to the off-label promotion of Topamax, paying criminal penalties and $75 million to settle an FCA case, available at https://www.justice.gov/opa/pr/two-johnson-johnson-subsidiaries-pay-over-81-million-resolve-allegations-label-promotion, last accessed January 14, 2021.

206. In the press release announcing the settlement with Merck related to the unlawful promotion of its drug Vioxx, the U.S. Attorney for Massachusetts stated: "The severity of these criminal and civil sanctions should serve as a reminder of this Office, and this department's unwavering commitment to holding drug companies fully accountable for failures to comply with their public safety and marketing obligations, and to recovering taxpayer funds that have gone towards the purchase of illegally marketed products." Pharmaceutical Company Merck Sharp & Dohme Sentenced in Connection with Unlawful Promotion of Vioxx, available at https://www.justice.gov/opa/pr/us-

pharmaceutical-company-merck-sharp-dohme-sentenced-connection-unlawful-promotion-vioxx, last accessed January 14, 2021.

207. FDA made it clear in its approval letters for Prezista and Intelence that the drugs must not be marketed for off-label uses such that "[m]arketing the product with FPL [final printed labeling] that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug."

HHS Guidelines

208. Further, the HHS Guidelines consistently noted throughout the Relevant Time Period that Prezista has a negative effect on lipids or causes hyperlipidemia.

Corporate Integrity Agreements with the Government

209. In 2010, a Janssen affiliate entered a five-year Corporate Integrity Agreement with HHS-OIG that obligated it to monitor sales representatives to ensure that the messages and materials delivered during sales calls were not off-label. The Corporate Integrity Agreement also required it to ensure its speaker programs did not contain off-label messages, including by reviewing the slide decks, the statements made during the program, and sales representatives' activities during the programs.

210. In 2013, Janssen itself (through its parent Johnson & Johnson) entered into a five-year Corporate Integrity Agreement that included similar requirements to control off-label promotions during sales calls on doctors and speaker programs.

B. Relators intend to prove the following contested facts with regard to damages:

Damages to the United States Government

1. About 70% of claims submitted for Prezista and Intelence were paid by Government payors like Medicare and Medicaid.

2. The United States Government is entitled to damages in the amount of $292,958,336[4] due to Janssen's violation of the False Claims Act stemming from its violations of the Anti-Kickback Statute, pursuant to Section 3729(a)(1)(A) of the False Claims Act.

3. The United States Government is entitled to damages in the amount of $447,013,756 due to Janssen's violation of the False Claims Act stemming from its off-label marketing and/or misbranding of Prezista and Intelence, pursuant to Sections 3729(a)(1)(A) and (B) of the False Claims Act.

4. According to the CMS data, hundreds of thousands of Prezista and Intelence prescriptions were written for off-label uses.

[4] The damages figures presented here vary slightly from those presented in the report of Relators' expert Professor Israel Shaked because (a) the damages to the federal Government and the Plaintiff States have been separated, and (b) the state portion of Medicaid payments from states without state false claims act laws have been removed. After removing the state portion of Medicaid payments from states without state false claims act laws, the total kickback damages (to the federal Government and the Plaintiff States) are lower by 0.29%, and the total off-label marketing damages are lower by 0.13%. A summary of all damages and claims to the federal Government and the Plaintiff States is presented in Exhibit A.

5. The total number of false claims that Janssen caused to be submitted to the United States Government stemming from its violations of the Anti-Kickback Statute, pursuant to Section 3729(a)(1)(A) of the False Claims Act, is 378,077.

6. The total number of false claims that Janssen caused to be submitted to the United States Government stemming from its off-label marketing of Prezista and Intelence, pursuant to Sections 3729(a)(1)(A) and (B) of the False Claims Act, is 536,803.

7. Janssen paid speakers in the form of honoraria and other compensation. Once a speaker was paid by Janssen, all Prezista and Intelence prescriptions made by that physician and reimbursed by Medicare, Medicaid, and ADAP Government payors, from the first payment date to the end of 2014, constitute damages to the Government. The amount reimbursed by the federal Government for Prezista prescriptions written by speakers is $225,169,827, and the number of claims Janssen caused to be submitted to the federal Government is 274,105. The amount reimbursed by the federal Government for Intelence prescriptions written by speakers is $67,788,509, and the number of claims Janssen caused to be submitted to the federal Government is 103,972.

8. All Prezista prescriptions written for patients who received any lipid regulating medicine or a lipid-related diagnosis prior to the first time they were prescribed Prezista constitute off-label claims for purposes of Relators' Prezista lipid neutral claim. The amount of the Prezista lipid neutral claims initially written by Influenced physicians[5] from the period of June 2006 to December 2014 reimbursed by the federal Government is $405,191,153, and the number of claims Janssen caused to be submitted to the federal Government is 478,802.

9. All Prezista prescriptions written for patients who did not have a prescription for another ARV medication prior to that patient's first Prezista prescription, and who did not receive a prescription for a non-Prezista ARV drug within 90 days following their first claim of any kind, constitute off-label claims for purposes of Relators' Prezista treatment naïve claim. The amount of Prezista treatment naïve claims initially written by Influenced physicians from the period of June 2006 to September 30, 2008, reimbursed by the federal Government is $1,699,573, and the number of claims Janssen caused to be submitted to the federal Government is 2,758.

10. All Intelence prescriptions written for patients who did not have a prescription for another ARV medication prior to that patient's first Intelence prescription, and who did not receive a prescription for a non-Intelence ARV drug within 90 days following their first claim of any kind, constitute off-label claims for purposes of Relators' Intelence treatment naïve claim. The amount of Intelence treatment naïve claims initially written by Influenced physicians for the period of 2008 to 2014 reimbursed by the federal Government is $14,996,971, and the number of claims Janssen caused to be submitted to the federal Government is 24,368.

11. All Intelence prescriptions with dosing instructions suggesting once-daily usage constitute off-label claims for purposes of Relators' Intelence once daily dosing claim.

[5] An "Influenced" physician is a physician who was contacted by Janssen in one of three ways: receiving a sales call from a Janssen representative, attending a speaking event, or speaking at a speaking event.

The amount of Intelence once-daily dosing claims for the period of 2008 to 2014 reimbursed by the federal Government is $41,822,603, and the number of claims Janssen caused to be submitted to the federal Government is 58,001.

12. The off-label claims that are included in Relators' damages calculation are claims to Government payors resulting from prescriptions initially written by an "Influenced" doctor. Life-long prescriptions of all patients whose first Prezista or Intelence prescription was written by an Influenced physician constitute off-label claims. An "Influenced" physician is a physician who was contacted by Janssen in one of three ways: receiving a sales call from a Janssen representative, attending a speaking event, or speaking at a speaking event.

13. Janssen paid 335 physicians to serve as speakers at its Speaker Programs. Speakers received between $750 to $3,000 per speaking event. Some doctors presented at over 200 events from 2006 to 2014, with some speakers receiving more than $400,000 in honoraria over this time period. The total honoraria for all speakers from June 2006 to 2014 is $14,099,650.

14. Speakers were also paid to train and instruct other doctors who were asked to join Janssen's Speaker Program. The total training fees from June 2006 to December 2014 is at least $688,050.

15. Speakers were paid reimbursements related to their speaking and training events, *i.e.*, travel, lodging, and meals. The speaker expenses from June 2006 to December 2014 total at least $1,571,968.

16. Speakers were paid consulting fees for participating at marketing events such as Advisory Board meetings. The total consulting fees amount to at least $644,857 from June 2006 to December 2014.

17. Janssen reimbursed speakers for expenses related to consulting events, *i.e.*, travel, lodging, and meals. The total consulting expenses amount to at least $269,461 from June 2006 to December 2014.

18. Total compensation paid to doctors on Janssen's Speaker Program amount to at least $17.25 million.

19. Relators will present the total compensation paid to each speaker who participated in the Speaker Program, and the number of speeches they each gave. Relators will also present information regarding the Prezista and Intelence prescriptions written by each speaker.

20. More than 90% of Janssen's paid speakers continued to prescribe Prezista and Intelence following their first speech.

21. Janssen typically selected high prescribers of Prezista and Intelence to be paid speakers.

22. Speakers accounted for 11.10% of all Prezista and Intelence prescriptions in dollars reimbursed by Government payors (constituting $327 million) while accounting for only 0.30% of the total population of physicians who prescribed at least one ARV drug.

23. An increase in compensation paid to speakers by Janssen caused the speakers to

prescribe more Prezista and Intelence.

24. Speakers were more likely to prescribe Prezista and Intelence than non-speakers.

25. Janssen's unlawful marketing activities caused Influenced physicians to prescribe higher proportions of off-label Prezista and Intelence prescriptions than non-Influenced physicians.

26. Influenced physicians, speech attendees, and speakers who are Infectious Disease Specialists prescribed statistically significantly higher rates of off-label Prezista and Intelence to all Prezista and Intelence than non-Influenced physicians, non-attendees, and non-speakers who are Infectious Disease Specialists.

27. Janssen's increasing number of contacts with physicians caused those physicians to prescribe higher proportions of off-label Prezista and Intelence prescriptions than physicians who received less marketing contacts. The off-label percentage of Prezista and Intelence to all Prezista and Intelence rates increases as the number of Janssen marketing contacts increases.

28. Influenced physicians, attendees, and speakers with five or more Medicare patients prescribed statistically significantly higher rates of off-label Prezista and Intelence to all Prezista and Intelence than non-Influenced physicians, non-attendees, and non-speakers with five or more Medicare patients.

29. Attending a Janssen sponsored speaking event caused physicians to prescribe higher proportions of off-label Prezista and Intelence prescriptions than not attending.

30. Being a paid speaker on Janssen's Speaker Bureau caused physicians to prescribe higher proportions of off-label Prezista and Intelence prescriptions than non-speakers.

31. Speakers account for 20.8% and 20.4% of all Prezista and Intelence off-label prescriptions and dollar amounts reimbursed by Medicare, respectively, while accounting for only 1.21% of all physicians who had at least one Prezista or Intelence prescription from June 2006 to December 20-14 paid by Medicare.

32. Influenced physicians with at least 1 ARV initiation make up 11.04% of the physician population that initiated at least 1 ARV patient. However, Influenced physicians initiated 65.64% of all Prezista patients. Influenced physicians with at least 1 ARV initiation make up 11.04% of the physician population that initiated at least 1 ARV patient. However, Influenced physicians initiated 69.01% of all Intelence patients.

33. Prezista sales increased substantially from 2009 ($592 million) to 2014 ($1,831,000) with a compound annual growth rate ("CAGR") of over 25% the same period. Compared to other protease inhibitors, the market share of Prezista was the fastest rising from mid-2011 to mid-2014, reaching a market share of 25.6% by the second quarter of 2014.

34. Intelence sales increased consistently from $243 million in 2010 to $379 million in 2013, at a CAGR of 16%.

Civil Penalties and Treble Damages

35. Under the federal False Claims Act, 31 U.S.C. 3729 *et seq.*, Janssen is liable for three times the amount of damages that the United States sustained because of its conduct. In addition, Janssen is liable for a civil penalty of not less than $5,500 and not more than $11,000 per false statement and/or claim (as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990). *See* 28 C.F.R. 85.3(a)(9). In addition to the damages under the federal FCA, Janssen is liable to the Plaintiff States for three times the amount of damages sustained by the Plaintiff States because of Janssen's conduct, plus civil penalties and any other recoveries or relief provided for and permitted by the individual State False Claims Acts.

Damages to Plaintiff States

36. The table in Exhibit A shows the amount Janssen caused the Plaintiff States (and the federal Government) to pay out for Prezista and Intelence prescriptions in violation of their respective false claims act laws stemming from Janssen's unlawful kickbacks to speakers and off-label marketing, as well as the number of illegal claims Janssen caused to be submitted to the Plaintiff States (and the federal Government).

Relators' Recovery

37. Relators Christine Brancaccio and Jessica Penelow are each entitled to the maximum amount permitted by law of the proceeds of this action collected by the United States and the Plaintiff States, plus reasonable expenses necessarily incurred, and reasonable attorneys' fees and costs. *See* 31 U.S.C. 3730(d)(1).

5. JANSSEN'S CONTESTED FACTS

A. Janssen intends to prove the following contested facts with regard to liability.

To succeed on their False Claims Act ("FCA") claims, the Relators must prove: (1) that the Government was defrauded when it paid for Prezista and Intelence, two medications that the Food and Drug Administration ("FDA") approved to treat HIV and that were prescribed to treat HIV-positive patients; and/or (2) that, in violation of the Anti-Kickback Statute ("AKS"), Janssen bribed healthcare providers to prescribe Prezista and Intelence. As described in Section 12 (Janssen's Legal Issues) below, the Relators must prove each essential element of their claims to prevail at trial.

Janssen disputes each of the Relators' Contested Facts in Section 4 above. Many of the

Relators' purported Contested Facts are demonstrably untrue, irrelevant to this False Claims Act case, or otherwise inadmissible. Certain of the Relators' purported Contested Facts are also improper because they include legal arguments or legal conclusions, encroach on the Court's exclusive purview to instruct the jury on the law, and/or reach the ultimate issues that the jury must decide. Janssen therefore reserves its rights to object in its contemplated pretrial motions or at trial to the admissibility of evidence related to each of the Relators' purported Contested Facts.

Janssen intends to prove at trial that it properly and truthfully promoted Prezista and Intelence to doctors and other healthcare providers directly (through meetings with doctors, commonly referred to as sales calls) and indirectly (through speaker programs). Janssen further intends to prove at trial that it properly paid doctors to serve as speakers. Janssen's speaker programs were lawful promotional programs that are common in the pharmaceutical industry, and Janssen intended its speaker programs to promote Prezista and Intelence to doctors, other healthcare providers, caregivers, and HIV-positive patients by educating them about Prezista, Intelence, and other issues affecting HIV treatment.

Janssen intends to prove the following contested facts with regard to liability.

Prezista and Intelence are effective and safe HIV medications.

1. Prezista and Intelence are effective, safe, and lifesaving HIV medications.

2. Doctors and other healthcare providers prescribed Prezista and Intelence because they are effective and safe, and the right medications for many HIV-positive patients.

3. Clinical trials and medical studies demonstrate that Prezista and Intelence are effective and safe HIV medications for HIV-positive patients.

4. The FDA approved Prezista and Intelence as effective and safe HIV medications for HIV-positive patients.

5. The FDA approved Prezista, a protease inhibitor ("PI"), under its Accelerated Approval Program for treatment-experienced patients (that is, patients who had previously taken antiretroviral medications) in June 2006. In October 2008, the FDA approved Prezista for treatment naïve patients (that is, patients who had not previously taken antiretroviral medications). From 2006 through 2014, the FDA approved 18 additional updates to Prezista's label.

6. The FDA approved Intelence, a non-nucleoside reverse transcriptase inhibitor ("NNRTI"), under its Accelerated Approval Program for treatment-experienced patients in January 2008. From 2008 through 2014, the FDA approved 9 additional updates to Intelence's label.

7. The Accelerated Approval Program allows the FDA to approve, on an expedited basis, medications that treat serious conditions and fill an unmet medical need.

8. The United States Department of Health and Human Services ("HHS") periodically publishes consensus-based guidelines that help physicians choose treatment regimens for their HIV patients, titled Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV ("HHS Guidelines"). HHS retains experts in HIV research and treatment, community members with knowledge of HIV care, and appointed representatives of relevant government agencies to evaluate available scientific research and to write and issue the HHS Guidelines.

9. The HHS Guidelines help doctors who treat HIV-positive patients select the best treatment regimens for their patients, considering each patient's unique health and personal

circumstances. Among other things, the HHS Guidelines provide guidance and recommendations based on FDA-approved HIV medications' effectiveness, safety profile, and tolerability.

10. HHS generally updates its Guidelines multiple times each year to incorporate, among other things, information published in peer-reviewed journals and data presented at major conferences.

11. The HHS Guidelines "reflect the federal government's position on the standard of care for the use of HIV medications as it evolved over time, based on an expert panel's independent evaluation of reliable scientific research."

12. Prezista has appeared in every edition of the HHS Guidelines since the FDA approved it in 2006.

13. Patients are to take Prezista with another HIV medication called ritonavir. Taking ritonavir with Prezista has a "boosting" effect, which makes Prezista more effective.

14. The HHS Guidelines recommended that nearly all PIs (including Reyataz) be boosted with ritonavir, even if the FDA-approved label does not require a booster.

15. The HHS Guidelines acknowledge—and it is well-known and understood among doctors and other healthcare providers who treat HIV-positive patients—that PIs (particularly when boosted with ritonavir) may have an "adverse effect on lipids."

16. In November 2008, the HHS Guidelines categorized Prezista as a "preferred PI." And, starting in December 2009, the HHS Guidelines listed Prezista and Reyataz boosted with ritonavir as the only two "preferred PI" medications. The HHS Guidelines did not recommend prescribing Reyataz without a booster.

17. The HHS Guidelines noted that Prezista was "preferred" (in part) because of its favorable lipid profile, and included information favorably comparing Prezista's lipid profile to boosted Reyataz's lipid profile.

18. Neither Prezista's FDA-approved label nor the HHS Guidelines warned that certain patients should not take Prezista because of its potential adverse effect on lipids.

19. The HHS Guidelines included Intelence starting in January 2008.

20. The October 14, 2011 HHS Guidelines described a study which concluded that using Intelence once-daily could be a good NNRTI option for some treatment-naïve patients.

21. Prezista and Intelence were the right HIV medications for many HIV-positive patients.

Janssen properly and truthfully promoted Prezista and Intelence.

22. Janssen properly and truthfully promoted Prezista and Intelence to doctors, other healthcare providers, caregivers, and HIV-positive patients.

23. Janssen promoted Prezista and Intelence to educate doctors and other healthcare providers about the medications and to increase the number of patients taking them.

24. Janssen did this directly through sales calls with doctors and other healthcare providers and indirectly through speaker programs.

25. Each department within Janssen had a role in the process.

26. Business Analytics sought to understand how doctors were treating HIV-positive patients and the reasons why doctors prescribed a particular medication.

27. Marketing brainstormed ideas on how to appropriately and more effectively promote Prezista and Intelence.

28. Janssen created promotional materials to aid sales calls and made slide decks to aid speaker programs.

29. Janssen's promotional materials and speaker slide decks were drafted, reviewed, edited, and approved by employees in a variety of departments, including Business Analytics, Marketing, Medical, Compliance, Regulatory, and Legal.

30. Janssen submitted its promotional materials and speaker slide decks to the FDA for review and comment through what is commonly referred to as the FDA's 2253 process.

31. The FDA had the opportunity to comment on Janssen's promotional materials and speaker slide decks and, when it did so, Janssen considered the FDA's comments and made further edits or changes as need be.

32. Once the FDA's comments were addressed, Janssen allowed its Sales organization to start using the promotional materials during sales calls and its speakers to use the speaker slide decks during speaker programs.

33. Janssen trained its Sales employees to use Janssen-approved promotional materials during sales calls. Janssen provided a variety of training, conducted by different departments. Janssen's training often included real-world role-play training.

34. From time to time, Janssen informed Sales employees about articles, studies, or other publicly available information that were not part of the Janssen-approved promotional materials but discussed Prezista, Intelence, or other information related to HIV treatment.

35. It was important to Janssen that its Sales employees were aware of the information that was also available to the doctors and other healthcare providers on whom they called.

36. When Janssen gave this type of information to Sales employees, Janssen told the employees (in writing and verbally) that the information was for their personal knowledge and not to be used promotionally during a sales call.

37. If a doctor or other healthcare provider asked a Sales employee about information not included in Janssen's approved promotional materials, the Sales employee could have the doctor complete a Medical Information Request ("MIR"). The MIR would be routed to and answered by Janssen's Medical department.

38. District managers, regional managers, and the national sales director oversaw, managed, and monitored Sales employees to ensure that information Sales employees shared with doctors and other healthcare providers was proper and truthful.

39. Business Analytics, Marketing, Medical, Compliance, Regulatory, and Legal department employees, as well as the executives in charge of Janssen's HIV business, also oversaw and monitored Sales employees to ensure that information shared with doctors and other healthcare providers was proper and truthful.

40. Janssen instructed its Sales employees that they were expected to (and must) abide by Janssen's policies and expectations regarding proper and truthful promotion.

41. Janssen used speaker programs to educate doctors, other healthcare providers, caregivers, and patients about Prezista, Intelence, and HIV-related issues. Janssen wanted its speaker programs to encourage the doctors and other healthcare providers in attendance to prescribe Prezista and Intelence to their HIV-positive patients more often.

42. Janssen conducted four types of speaker programs: (1) Prezista speaker programs; (2) Intelence speaker programs; (3) Disease Awareness Speaker Bureau ("DASB") programs (which did not discuss any particular HIV medication, but covered HIV-related topics

generally); and (4) Community Speaker Bureau ("CSB") programs (which were geared toward HIV-positive patients, their caregivers, and others involved in HIV care).

43. Speaker programs are common in the pharmaceutical industry and play an important and beneficial role in disseminating promotional messages and providing educational content. For HIV in particular, the National HIV/AIDS Strategy for the United States is: "We must also ensure that all health and wellness practitioners (peer counselors, intake specialists, healthcare providers, nurses, and other health professionals) are also educated about HIV, especially in programs for underserved communities."

44. Janssen considered its business needs for speaker programs and set parameters and budgets for speaker programs that met those needs.

45. Janssen's business needs considered (among other things) that Prezista and Intelence were brand new medications (and that Prezista's and Intelence's FDA approvals changed several times), that HIV was a rapidly evolving disease, and that there were thousands of doctors, other healthcare providers, and patients that Janssen wanted to reach.

46. Janssen employees from the Marketing, Medical, Regulatory, Legal, and Compliance departments worked collaboratively to plan for and implement Janssen's speaker programs. Among other things, the cross-functional team considered the rationale for (and goals of) the speaker programs, speaker program content, the anticipated number of programs and speakers, speaker compensation, speaker training, and speaker selection.

47. Janssen selected qualified doctors to serve as speakers, considering (among other things) the doctors' training and work experience, their academic and clinical research, their clinical experience, their presentation skills, and their experience prescribing HIV medications, including Prezista and Intelence.

48. Janssen did not select doctors to serve as speakers to reward the doctors for past prescriptions or to encourage the doctors to prescribe more in the future.

49. Janssen employees in the Sales department could recommend that a particular doctor be considered as a speaker, but the cross-functional team (which did not include Sales) made the final determination as to who would be selected as speakers.

50. Janssen required its speakers to sign contracts, to complete training, to conduct at least three speaker programs a year, and to abide by Janssen's policies.

51. Janssen paid its speakers fair market value for their time and services (between $250 and $2,500, in line with industry standards), and capped annual speaker compensation (also in line with industry standards).

52. Speakers who did not complete the requisite number of programs or abide by Janssen's policies were retrained or removed from Janssen's speaker bureau as appropriate.

53. Among other things, Janssen required speakers to present the Janssen-approved and FDA-submitted speaker slide decks. Speakers could answer program attendees' questions about content not included in the speaker slide decks based on the speakers' own professional experience and opinion.

54. Janssen held speaker programs at medical offices or restaurants that were appropriate for a professional program. When speaker programs included food, Janssen capped the amount per person ($125 for a dinner program at a restaurant, in line with industry standards).

55. Speaker program attendees were doctors, other healthcare providers, caregivers, or HIV-positive patients. All were appropriate attendees for speaker programs.

56. Sales employees attended each speaker program and were required to report any potential violations of Janssen's policies.

57. From time to time, Janssen employees from other departments (including Compliance) attended speaker programs too.

58. Janssen used well-respected third-party vendors to track, monitor, and organize speaker programs, which ensured that (i) speakers were properly trained; (ii) speakers did not exceed the annual compensation cap; (iii) speaker program venues were appropriate; (iv) food and beverage costs were at or below the policy limitations; and (v) speaker programs complied with Janssen's policies.

59. Janssen analyzed whether its speaker programs were an effective way to promote Prezista and Intelence. These types of analyses are commonly referred to as return-on-investment ("ROI") analyses, and Janssen intentionally considered only how *attending* a speaker program may have impacted prescribing. Janssen intentionally *excluded* the speaker from this analysis.

Doctors and other healthcare providers prescribed Prezista and Intelence to HIV-positive patients for a variety of patient- and doctor-specific reasons.

60. HIV treatment is uniquely and highly individualized. A regimen that is appropriate for one patient may be inappropriate for another.

61. By using different HIV medications, in different combinations, doctors and other healthcare providers design individualized regimens for each patient based on a variety of considerations, including the patient's drug resistance, viral load, CD4 count, potential adverse effects, drug interactions, comorbidities, pregnancy or potential for pregnancy, patient preferences, adherence potential, tolerability, convenience, and cost.

62. Doctors and other healthcare providers closely monitor HIV-positive patients and require they undergo regular blood testing. Blood tests that measure the patient's viral load and CD4 counts tell the treating doctor whether the prescribed HIV treatment regimen is working—that is, the blood tests measure whether the patient is experiencing virologic failure (an increase in the viral load above an established threshold) or immunologic failure (a decrease in the CD4 cell count below an established threshold).

63. Doctors and other healthcare providers also closely monitor HIV patients for potential side effects, including side effects that may pose other health or quality of life challenges.

64. Doctors may switch an HIV patient's treatment regimen if the patient experiences virologic failure, immunologic failure, or side effects.

65. Why a doctor chooses one HIV treatment over another is complex and fact-dependent.

66. When deciding how to best treat their patients' HIV, doctors consider a number of factors, including patient-driven factors (e.g., comorbidities, drug tolerability and interactions, and history of medication adherence), experience-driven factors (e.g., the healthcare provider's own professional experience, medical training, and knowledge of scientific literature and clinical guidelines (including the HHS Guidelines)), and drug-specific factors (e.g., tolerability, convenience, drug-to-drug interactions, and potential adverse events). Doctors also may consider pharmaceutical promotion (e.g., Janssen's promotion of Prezista or Intelence, Bristol Myers Squibb's promotion of Reyataz, ViiV Healthcare's promotion of Epivir or Retrovir, and Boehringer Ingelheim's promotion of Viramune or Aptivus).

67. Relators collected, and intend to introduce at trial, data that they claim proves that Janssen's promotion was a substantial factor when doctors chose Prezista or Intelence. It does not. None of the data can reliably identify what doctors considered when prescribing Prezista or Intelence, let alone whether Janssen's promotion (even if improper or untruthful) was a substantial factor in the prescribing decision.

68. Relators proffer experts that they claim prove that Janssen's promotion was a substantial factor when doctors chose Prezista or Intelence. They do not. None of the experts can testify about what doctors considered when prescribing Prezista or Intelence, let alone whether Janssen's promotion (even if improper or untruthful) was a substantial factor in the prescribing decisions.

69. Instead, the doctors and other healthcare providers who interacted with Janssen or served as Janssen speakers prescribed Prezista and Intelence because they believed they were the right medications to treat their HIV patients.

It is the United States' policy to pay for HIV medications for HIV-positive patients.

70. During the relevant time period, Medicare, state Medicaids, and state ADAPs (AIDS Drug Assistance Programs) paid for Prezista and Intelence prescriptions for HIV-positive patients. Medicare, Medicaid, and ADAP continue to pay for Prezista and Intelence prescriptions for HIV-positive patients today.

71. It is the United States's policy—implemented at the federal and state levels through CMS—that Medicare, Medicaid, and ADAPs pay for HIV medications for HIV-positive patients.

72. Because HIV was a deadly epidemic, the federal government set up a special payment system to ensure that HIV-positive patients had easy access to HIV medications,

including Prezista and Intelence, and that prescription costs were covered by government insurance programs.

73. It is a strategic and general policy goal stated by the White House Office of National AIDS Policy that "[f]ederal and state governments should ensure access to appropriate HIV treatment by promoting unimpeded coverage of all HIV medications included in the HHS HIV Treatment Guidelines."

74. The policy further advises that "[p]ublic and private insurers and health care providers must also take steps to ensure that all HIV care providers have the knowledge and training to provide quality HIV care consistent with the latest treatment guidelines."

75. Medicare Part D provides prescription drug coverage for the elderly and people with certain disabilities.

76. Under Part D, the federal government helps to cover the costs of "covered Part D drugs," which are FDA-approved medications prescribed for a "medically accepted indication."

77. Part D does not require that a drug be "reasonable and necessary" to be covered under the benefit.

78. A "medically accepted indication" under Part D is any use that is FDA-approved or that is supported by citations in specified compendia.

79. The Medicare Prescription Drug Benefit Manual states that the "medically-accepted indication refers to the diagnosis or condition for which a drug is being prescribed, not the dose being prescribed for such indication."

80. While Part D generally must cover only two FDA-approved medications in a given therapeutic class, HIV medications are a special case. The government requires that Part

D reimburse "all or substantially all" HIV medications to ensure uninterrupted therapy to vulnerable patients.

81. Since Part D's inception, CMS's stated priority has been to ensure that beneficiaries have timely access to covered Part D drugs. This priority is especially true for HIV-positive patients—CMS generally opposes implementing utilization management tools (such as requiring prior authorizations) for HIV medications.

82. The Medicare Prescription Drug Benefit Manual states: "For HIV/AIDS drugs, utilization management tools such as prior authorization and step therapy are generally not employed in widely used, best practice formulary models."

83. Medicaid, which provides healthcare coverage for low-income people, is jointly funded by federal and state governments.

84. The federal government allows state Medicaid programs to cover any medication that is a "prescribed drug"—that is, a medication "prescribed for the cure, mitigation, or prevention of a disease, or for health maintenance"—and that is prescribed by a doctor and dispensed by a pharmacy.

85. State Medicaid programs may choose not to cover a medication that "is not for a medically accepted indication."

86. For patients to realize the public health benefits of HIV therapies, CMS, HHS, the Health Resources & Services Administration ("HRSA"), and the Centers for Disease Control and Prevention ("CDC") direct state Medicaid programs to align their Medicaid policies and practices with the HHS Guidelines.

87. States create and administer their own ADAP programs through federal block grants that fund "core medical services" for HIV-positive patients, including HIV medications.

88. The purpose of the ADAPs is to ensure that low-income HIV patients who do not qualify for Medicare, Medicaid, or private insurance—or whose health insurance provides insufficient coverage—have access to their prescribed HIV medications.

89. Ultimately, state ADAP programs serve as "payors of last resort" to improve the availability of and access to care for uninsured or underinsured HIV patients, and fund HIV treatment when no other resources are available to them.

90. Medicare, Medicaid, and ADAP (through guidance, policies, regulations and laws) set out to pay for HIV medications (including for Prezista and Intelence) when prescribed to treat HIV-positive patients.

***Relators and their witnesses are not credible*.**

1. The Relators are not credible and are not believable.

2. The Relators' testimony is motivated by their self-interest and biases.

3. Sara Strand, Mark Wilhelm, Donna Graham, Joseph Holshoe, Matthew Grooms, and Russ Moyer are not credible and are not believable.

4. The testimony of Ms. Strand, Mr. Wilhelm, Ms. Graham, Mr. Holshoe, Mr. Grooms, and Mr. Moyer is motivated by their self-interest and biases.

B. Janssen intends to prove the following contested facts with regard to damages.

Even if the Relators can prove that Janssen violated the False Claims Act, the Relators must separately prove that the Government (that is, Medicare, Medicaid, and ADAP) suffered actual damages. As described in Section 12 (Janssen's Legal Issues), the Relators must prove damages by a preponderance of the evidence. The measure of damages in this case is the difference between the amount of money the Government paid for Prezista and Intelence and the value of what the Government actually received.

The Relators rely on their purported expert, Israel Shaked, to proffer a damages model that is contradicted by the facts of this case, that is not supported by the facts in this case, and/or is contrary to the law.

Janssen intends to prove the following contested facts with regard to damages.

Professor Shaked relied on incomplete or improper data sets to identify claims for reimbursement that he opined violated the False Claims Act and that he opined must be included in damages.

1. Professor Shaked relied on diagnostic codes in CMS claims data to identify patients that may have had "lipid issues." Professor Shaked included in damages any prescription written for any HIV-positive patient who, at any time prior to starting Prezista, was evaluated or treated for a lipid-related issue at least once (what Professor Shaked deems "Lipid Neutral Claims").

2. Relators' and Professor Shaked's reliance on the CMS claims data is not consistent with the practice of medicine. The CMS claims data is a partial record of patients' medical bills. An indication within the CMS data that a patient was evaluated or even treated for lipid-related issues and was subsequently prescribed Prezista is unremarkable because (among other reasons) Prezista is the right medication for many HIV-positive patients with lipid conditions.

3. Professor Shaked also improperly included patients who only may have been tested for (but did not actually have) lipid conditions, or who may have had a lipid condition that resolved well before the patient was prescribed Prezista.

4. Dr. Anupam Jena will explain the limitations of the CMS claims data and correct Professor Shaked's overbroad definition of "lipid claims."

5. Professor Shaked also relied on the CMS claims data for Prezista and Intelence to identify what he deems "Treatment Naïve Claims." Professor Shaked improperly included patients who may not have been treatment-naïve.

6. Dr. Jena will explain the limitations of the CMS claims data and that complete patient medical records are the only reliable source to determine whether a patient is treatment-naïve. Dr. Jena will more accurately identify potentially treatment naïve patients by correcting Professor Shaked's overbroad definition of "Treatment Naïve Claims."

7. For what Professor Shaked deems as Intelence "Once-Daily Dosing Claims," Professor Shaked used limited pharmacy data to estimate the rate at which healthcare providers prescribed Intelence for once-daily use. Professor Shaked made a series of unsupported assumptions to estimate the number of "Once-Daily Dosing Claims."

8. Dr. Jena will explain that the pharmacy data has several limitations, including: (1) only records from three pharmacies (BioScrip, Rite Aid, and Walgreens) were analyzed; (2) the pharmacy data does not identify the prescribing doctor; (3) the pharmacy data does not include dosing instructions for every prescription; and (4) even when dosing instructions are included, the instructions are not necessarily clear or consistent. Dr. Jena also will correct errors in Professor Shaked's methodology used to calculate Once-Daily Dosing Claims.

Professor Shaked's damages methodology relied on factual assumptions that are contradicted or not supported by the facts in this case.

9. The Relators' attorneys provided Professor Shaked with factual assumptions that are untrue or unsupported.

10. Professor Shaked testified that he adopted the Relators' attorneys' assumptions to render his opinions, and took no steps to verify whether the assumptions were true, accurate, reliable, or otherwise supported by the facts in this case.

11. As a result, because the assumptions on which Professor Shaked relied are untrue or unsupported, his opinions are unreliable and flawed.

12. The Relators' attorneys told Professor Shaked to assume that every time a Janssen Sales employee called on a doctor, that Sales employee delivered all four promotional messages that the Relators claim were improper. That assumption is not supported by the facts in this case and is contradicted by, among other things, Ms. Penelow's testimony (for example).

13. The Relators' attorneys told Professor Shaked to assume that every doctor who had contact with Janssen—because Janssen Sales employees called on the doctor or because the doctor attended a speaker program—had their medical judgment permanently hijacked. That assumption is not supported by the facts in this case and is contradicted by doctors who had contact with Janssen.

14. The Relators' attorneys told Professor Shaked to assume that every doctor who Janssen paid as a speaker had their medical judgment permanently hijacked, even when prescribing to patients who already were on a Prezista or Intelence treatment regimen when the doctor-speaker began treating the patients. That assumption is not supported by the facts in this case and is contradicted by doctors who served as speakers.

15. The Relators' attorneys told Professor Shaked to assume that if a patient was first prescribed Prezista or Intelence in ways that Professor Shaked assumes are "off-label" by a doctor who received a sales call or attended a speaker program, that patient's lifelong supposed "off-label" Prezista and Intelence prescriptions were caused by Janssen's supposed improper promotion. The Relators' attorneys told Professor Shaked to use this assumption, even if the patient later was prescribed Prezista or Intelence by a doctor who never received a sales call and never attended a speaker program. In other words, only the doctor who starts a patient on

Prezista or Intelence matters to Professor Shaked. This assumption is not supported by the facts in this case.

16. The Relators' attorneys told Professor Shaked to use a different assumption for speaker programs. The Relators' attorneys told Professor Shaked to assume that if a patient was prescribed Prezista or Intelence by a doctor who was not a speaker, but then switched doctors and was treated by a doctor-speaker, the doctor-speaker's Prezista or Intelence prescriptions were caused by Janssen's payments to the speaker. In other words, now the doctor who starts a patient on Prezista or Intelence does not matter to Professor Shaked. This assumption is not supported by the facts in this case.

17. Professor Shaked did not develop any of these assumptions and does not have the requisite education or professional experience to opine on whether these assumptions are accurate or supported by the facts.

18. Building on his incorrect and unsupported assumptions, Professor Shaked performed a simplistic correlation analysis that does not account for any confounding factors to opine that Janssen caused every Prezista or Intelence prescription that he has deemed improper and prescribed in violation of the False Claims Act.

19. Professor Shaked assumed (without analysis) that Medicare's, Medicaid's, and ADAP's actual damages are the full amounts that those government health insurance programs paid for those supposedly improper and unlawful prescriptions.

Dr. Jena will deduct Prezista and Intelence claims that were not caused by Janssen and/or did not result in damages to the Government.

20. Dr. Jena, using his experience and expertise as a doctor and economist, will remove claims for reimbursement for Prezista or Intelence prescriptions that Janssen did not cause, and/or that did not result in damages to the Government.

21. Dr. Jena's deductions are necessary to estimate the Government's actual damages, if any.

22. Dr. Jena's deductions include:

i. Prezista and Intelence prescriptions that were likely written because patients needed to take Prezista or Intelence.

ii. Prezista and Intelence prescriptions to patients who were successfully treated with Prezista or Intelence.

iii. Prezista and Intelence prescriptions written by doctors who had successfully treated other patients with Prezista or Intelence.

iv. Medicaid rebates—that is, money that Janssen credited to Medicaid for Prezista and Intelence.

v. Prezista and Intelence prescriptions when the Government received the benefit of the bargain because patients were successfully treated with Prezista or Intelence.

vi. The cost of alternative HIV medications.

23. Dr. Jena will further correct several errors Professor Shaked made when applying his proffered methodologies to reach his opinions.

24. Dr. Jena's analyses—which accurately rely on the facts in this case—will substantially reduce the maximum potential damages in this case.

6. RELATORS' WITNESSES (Aside from those called for impeachment purposes, only those witnesses whose names and addresses are listed below will be permitted to testify at trial).

A. On liability, Relators intend to call the following fact witnesses who will testify in accordance with the following summaries:

1. **Relator Christine Brancaccio**, 14 Whitehall Court, Holbrook, NY 11741. Ms.

Brancaccio worked as a Janssen sales representative from 2006 to 2014 in the New York One District, which encompassed the territories of Long Island and Queens. She continues to work at Janssen today. She is expected to testify in conformity with the factual allegations in her Second Amended Complaint, discovery responses, and deposition testimony. In general, her testimony will include facts regarding: Janssen's company-wide off-label marketing and Speaker Program/kickback schemes relating to its prescription HIV/AIDS treatment drugs Prezista and Intelence; Prezista's and Intelence's FDA approved uses and indications, and limited marketability; senior personnel's illegal efforts and directives given to Janssen employees aimed toward increasing sales of these drugs; Janssen's pressure on sales representatives and others to participate in the off-label marketing and kickback schemes; off-label marketing that occurred on sales calls, which included the improper use of off-label studies and improper use of Medical Information Request forms; Janssen's tracking of doctors' prescriptions before and after sales calls and paid speeches; the effect of off-label promotion on doctors' prescription behavior and sales; Janssen's use of Return on Investment analyses; the Janssen's use and improper implementation of the Speaker Program as a means to induce (and/or reward) paid doctors to prescribe Prezista and Intelence, including for off-label purposes, and to disseminate off-label information to doctors; the practice of not reporting off-label marketing activity out of fear of retaliation; the practice of not committing illegal or improper practices to writing; and Janssen's submission of false claims for reimbursement to Government Health Care Programs.

2. **Relator Jessica Penelow**, 30 Heron Road, Livingston, NJ 07039. Ms. Penelow served as a Janssen sales representative from 2006 to 2013 in the New York One District for the lower east side of Manhattan territory. She was forced out of Janssen in 2013 because of the pressure to promote the drugs off label. She is expected to testify in conformity with the factual allegations in her Second Amended Complaint, discovery responses, and deposition testimony. In general, her testimony will include facts regarding: Janssen's company-wide off-label marketing and Speaker Program/kickback schemes relating to its prescription HIV drugs Prezista and Intelence; Prezista's and Intelence's FDA approved uses and indications, and limited marketability; senior personnel's illegal efforts and directives given to Janssen employees aimed toward increasing sales of these drugs; Janssen's pressure on sales representatives and others to participate in the off-label marketing and kickback schemes; off-label marketing that occurred on sales calls, which included the improper use of off-label studies and improper use of Medical Information Request forms; Janssen's tracking of doctors' prescriptions before and after sales calls and paid speeches; the effect of off-label promotion on doctors' prescription behavior and sales; Janssen's use of Return on Investment analyses; Janssen's use and improper implementation of the Speaker Program as a means to induce (and/or reward) paid doctors to prescribe Prezista and Intelence, including for off-label purposes, and to disseminate off-label information to doctors; the practice of not reporting off-label marketing activity out of fear of retaliation; the practice of not committing illegal or improper practices to writing; and Janssen's submission of false claims

for reimbursement to Government Health Care Programs.

3. **Mark Wilhelm**, 24954 North Turkey Creek Road, Evergreen, CO 80439. Mr. Wilhelm served as a Key Account Director for the West from 2006 to 2009, whereby he oversaw all of the Key Account Managers, sales representatives, doctors' accounts, and sales of Prezista and Intelence in 30 states in the West. He is expected to testify in conformity with his deposition testimony. In general, his testimony will include the facts regarding: Janssen's company-wide off-label marketing and Speaker Program/kickback schemes relating to its prescription HIV drugs Prezista and Intelence; Prezista's and Intelence's FDA approved uses and indications, and limited marketability; Prezista's initial sales being far below forecasts; senior executives' illegal efforts and directives given to Janssen employees aimed toward increasing sales of these drugs; Janssen's pressure on sales representatives and others to participate in the off-label marketing and kickback schemes; off-label marketing that occurred on sales calls, which included the improper use of off-label studies and improper use of Medical Information Request forms; Janssen's tracking of doctors' prescriptions before and after sales calls and paid speeches; the effect of off-label promotion on doctors' prescription behavior and sales; Janssen's use of Return on Investment analyses; Janssen's use and improper implementation of the Speaker Program, Advisory Board meetings, training sessions, and other marketing events as a means to induce (and/or reward) paid doctors to prescribe Prezista and Intelence, including for off-label purposes, and to disseminate off-label information to doctors; Janssen's company-wide practice of not committing illegal or improper practices to writing; and Janssen's submission of false claims for reimbursement to Government Health Care Programs.

4. **Sara Strand**, 21 East Huron Street, #805, Chicago, IL 60611. Ms. Strand served as the Regional Business Director for the East from 2006 to 2011, where she oversaw District Managers, sales representatives, doctors' accounts, and sales of Prezista and Intelence in the East. She is expected to testify in conformity with her deposition testimony. In general, her testimony will include the facts regarding: Janssen's company-wide off-label marketing and Speaker Program/kickback schemes relating to its prescription HIV drugs Prezista and Intelence; Prezista's and Intelence's FDA approved uses and indications, and limited marketability; Prezista's initial sales being far below forecasts; senior executives' illegal efforts and directives given to Janssen employees aimed toward increasing sales of these drugs; Janssen's pressure on sales representatives and others to participate in the off-label marketing and kickback schemes; off-label marketing that occurred on sales calls, which included the improper use of off-label studies and improper use of Medical Information Request forms; Janssen's tracking of doctors' prescriptions before and after sales calls and paid speeches; the effect of off-label promotion on doctors' prescription behavior and sales; Janssen's use of Return on Investment analyses; Janssen's use and improper implementation of the Speaker Program, Advisory Board meetings, training sessions, and other marketing events as a means to induce (and/or reward) paid doctors to prescribe Prezista and Intelence,

including for off-label purposes, and to disseminate off-label information to doctors; Janssen's company-wide practice of not committing illegal or improper practices to writing; and Janssen's submission of false claims for reimbursement to Government Health Care Programs.

5. **Donna Graham**, 24954 North Turkey Creek Road, Evergreen, CO 80439. Ms. Graham served as a sales representative from 2006 to 2007 and then 2009 to 2011, and as Janssen's National Sales Trainer from 2007 to 2009 where she trained all of the sales representatives and Key Account Managers across the country how to promote Prezista and Intelence. She is expected to testify in conformity with her deposition testimony. In general, her testimony will include the facts regarding: Janssen's company-wide off-label marketing and Speaker Program/kickback schemes relating to its prescription HIV drugs Prezista and Intelence; Prezista's and Intelence's FDA approved uses and indications, and limited marketability; senior executives' illegal efforts and directives given to Janssen employees aimed toward increasing sales of these drugs, including their directives given directly to her to train sales representatives and others to promote the drugs for off-label purposes; Janssen's pressure on sales representatives and others to participate in the off-label marketing and kickback schemes; off-label marketing that occurred on sales calls, which included the improper use of off-label studies and improper use of Medical Information Request forms; Janssen's tracking of doctors' prescriptions before and after sales calls and paid speeches; the effect of off-label promotion on doctors' prescription behavior and sales; Janssen's use of Return on Investment analyses; Janssen's use and improper implementation of the Speaker Program, Advisory Board meetings, training sessions, and other marketing events as a means to induce (and/or reward) paid doctors to prescribe Prezista and Intelence, including for off-label purposes, and to disseminate off-label information to doctors; Janssen's company-wide practice of not committing illegal or improper practices to writing; and Janssen's submission of false claims for reimbursement to Government Health Care Programs.

6. **Matthew Grooms**, 10810 Northeast 106th Terrace, Kansas City, MO 64157. Mr. Grooms served as a sales representative from 2006 to 2010 who sold Prezista and Intelence to doctors in states located in the Mid-South District. He is expected to testify in conformity with his deposition testimony. In general, his testimony will include facts regarding: Janssen's company-wide off-label marketing and Speaker Program/kickback schemes relating to its prescription HIV drugs Prezista and Intelence; Prezista's and Intelence's FDA approved uses and indications, and limited marketability; senior personnel's illegal efforts and directives given to Janssen employees aimed toward increasing sales of these drugs; Janssen's pressure on sales representatives and others to participate in the off-label marketing and kickback schemes; off-label marketing that occurred on sales calls, which included the improper use of off-label studies and improper use of Medical Information Request forms; Janssen's tracking of doctors' prescriptions before and after sales calls and paid speeches; the effect of off-label promotion on doctors' prescription behavior and sales; Janssen's use of

Return on Investment analyses; Janssen's use and improper implementation of the Speaker Program as a means to induce (and/or reward) paid doctors to prescribe Prezista and Intelence, including for off-label purposes, and to disseminate off-label information to doctors; the practice of not committing illegal or improper practices to writing; and Janssen's submission of false claims for reimbursement to Government Health Care Programs.

7. **Joseph Holshoe**, 1315 Bastogne Court, Fort Wainwright, AK 99703. Mr. Holshoe served as a sales representative from 2006 to 2009 who sold Prezista and Intelence to doctors in states located in the New England District. He is expected to testify in conformity with his deposition testimony. In general, his testimony will include the facts regarding: Janssen's company-wide off-label marketing and Speaker Program/kickback schemes relating to its prescription HIV drugs Prezista and Intelence; Prezista's and Intelence's FDA approved uses and indications, and limited marketability; senior executives' illegal efforts and directives given to Janssen employees aimed toward increasing sales of these drugs; Janssen's pressure on sales representatives and others to participate in the off-label marketing and kickback schemes; off-label marketing that occurred on sales calls, which included the improper use of off-label studies and improper use of Medical Information Request forms; Janssen's tracking of doctors' prescriptions before and after sales calls and paid speeches; the effect of off-label promotion on doctors' prescription behavior and sales; Janssen's use of Return on Investment analyses; Janssen's use and improper implementation of the Speaker Program as a means to induce (and/or reward) paid doctors to prescribe Prezista and Intelence, including for off-label purposes, and to disseminate off-label information to doctors; the practice of not committing illegal or improper practices to writing; and Janssen's submission of false claims for reimbursement to Government Health Care Programs.

8. **Michael Schiff**, 1220 Fair Oaks Avenue, Oak Park, IL 60302. Michael Schiff is the corporate representative of nonparty Partners in Loyalty Marketing, Inc. ("PILM"). He is expected to testify in conformity with his deposition testimony. His expected testimony will include the facts regarding PILM's Return on Investment analyses ("ROI") performed for Janssen in connection with its Speaker Program, the PILM reports about ROI, and Janssen's purpose behind its Speaker Program as it relates to doctors' prescriptions.

9. **Michael Iacobellis**, 4475 Allegiance Street, Center Valley, PA 18034. Mr. Iacobellis was the National Sales Director from April 2008 to June 2011, where he led the sales organization relative to their products. He is expected to testify in conformity with his deposition testimony. This includes facts regarding: Janssen's marketing and sale of Prezista and Intelence; that Prezista was Janssen's first HIV drug on the market; Prezista's and Intelence's FDA approved uses and indications, and limited marketability; Prezista's sales being below forecasts after its launch; discussions and meetings among senior executives and others on how to promote and market the drugs in order to increase their sales; Janssen's expectations, monitoring, and evaluation of sales

representatives regarding sales; Janssen's tracking of doctors' prescriptions, including speakers; Janssen's use of and tracking of Medical Information Request forms; Janssen's use and implementation of the Speaker Program which was aimed toward increasing paid speakers' and attendees' prescriptions; Janssen's use and implementation of Advisory Boards; Janssen's targeting of doctors who accounted for the majority of prescription volume; Janssen's tracking of sales, including off-label sales; Janssen's use of marketing research reports and their findings; and the submission of claims to Government Health Care Programs.

10. **Glenn Mattes**, 4524 Everview Drive, Doylestown, Pa. 18902. Mr. Mattes was Janssen's President from 2006 to 2011. He is expected to testify in conformity with his deposition testimony. This includes facts regarding: Janssen's marketing and sale of Prezista and Intelence; that Prezista was Janssen's first HIV drug on the market; Prezista's and Intelence's FDA approved uses and indications, which limited the drugs' marketability and sales; Prezista's sales being below forecasts after its launch; discussions and meetings among senior executives and others regarding the drugs' uses and unapproved off-label uses, and how to promote and market the drugs in order to increase their sales; Janssen's expectations, monitoring, and evaluations of sales representatives regarding sales; Janssen's tracking of doctors' prescriptions, including speakers' prescriptions; Janssen's use of and tracking of Medical Information Request forms; the use of marketing research reports and their findings; Janssen's tracking of sales, including off-label sales; Janssen's use and implementation of the Speaker Program which caused an increase in paid speakers' and attendees' prescriptions; Janssen's use and implementation of Advisory Boards; Janssen's analysis of Return on Investment relating to its Speaker Program; Janssen's Corporate Integrity Agreements and Certificates of Compliance; and the submission of claims to Government Health Care Programs.

11. **Mark Gossett**, 316 Valdez Avenue, Half Moon Bay, Ca. Mr. Gossett served as Janssen's Vice President of Sales and Marketing from March 2007 to January 2010. He is expected to testify in conformity with his deposition testimony. This includes facts regarding: Janssen's marketing and sale of Prezista and Intelence; that Prezista was Janssen's first HIV drug on the market; Prezista's and Intelence's FDA approved uses and indications, which limited the drugs' marketability and sales; Prezista's sales being below forecasts after its launch; discussions and meetings among senior executives and others regarding the drugs' uses and unapproved off-label uses, and how to promote and market the drugs in order to increase their sales; the drugs' approved and unapproved market segments; Janssen's expectations, monitoring, and evaluations of sales representatives regarding sales; Janssen's tracking of doctors' prescriptions, including speakers' prescriptions; Janssen's use of and tracking of Medical Information Request forms; the use of marketing research reports and their findings; Janssen's use and funding of off-label studies; Janssen's tracking of sales, including off-label sales; Janssen's long term planning and sales forecasts, including for off-label uses; Janssen's use and implementation of the Speaker

Program which caused an increase in paid speakers' and attendees' prescriptions; Janssen's use and implementation of Advisory Boards; Janssen's analysis of Return on Investment relating to its Speaker Program; Janssen's Certificates of Compliance; and the submission of claims to Government Health Care Programs.

12. **Nancy Bartnett**, 323 Avenue A, Bayonne, NJ. Ms. Bartnett served as a Key Account Manager at Janssen beginning in 2006. She was later assigned to oversee the New York District around 2009. She is currently employed by Janssen. Ms. Bartnett is expected to testify in conformity with her deposition testimony. This includes facts regarding: Janssen's marketing and sale of Prezista and Intelence; Prezista's and Intelence's FDA approved uses and non-approved uses; discussions and meetings regarding how to promote and market the drugs in order to increase their sales; Janssen's monitoring and evaluation of sales representatives regarding sales; her oversight of and participation on sales calls and promotion of the drugs; Janssen's use of off-label studies; Janssen's tracking of doctors' prescriptions, including speakers; Janssen's use of and tracking of Medical Information Request forms; Janssen's tracking of sales; Janssen's use and implementation of the Speaker Program, including whether the Program was used to disseminate off-label information; Return on Investment analyses regarding the Speaker Program; and Janssen's use and implementation of Advisory Boards.

13. **Anthony Dolisi**, 112 Coverly Place, Melville, NY 11747. Mr. Dolisi was a director of health sciences at Janssen in 2005 to 2006, a Key Account Director for the East in 2007 to 2008, and a District Manager from 2009 to 2015. As a Key Account Director, he handled key accounts in the Northeast. As a District Manager, he was responsible for New York South, which included Staten Island, Brooklyn, Queens, and Long Island. In that role, he oversaw the sales activities of the two Relators. Mr. Dolisi is expected to testify in conformity with his deposition testimony. This includes facts regarding: Janssen's marketing and sale of Prezista and Intelence; Prezista's and Intelence's FDA approved uses and non-approved uses; Prezista's sales being below forecasts; discussions and meetings with senior management and others regarding how to promote and market the drugs in order to increase their sales; Janssen's monitoring, evaluation, and compensation of sales representatives regarding sales; his oversight of Relators' sales calls and promotion of the drugs; Janssen's dissemination of off-label studies and information to sales representatives; Janssen's tracking of doctors' prescriptions, including speakers; Janssen's use of and tracking of Medical Information Request forms; Janssen's use and implementation of the Speaker Program, including whether the Program was used to disseminate off-label information; Janssen's marketing efforts aimed toward institutions; Return on Investment analyses regarding the Speaker Program; and Janssen's use and implementation of Advisory Boards. Mr. Dolisi refused to answer any questions posed by the Government as part of a Civil Demand Investigation, whereby he exercised his right against self-incrimination under the Fifth Amendment.

14. **Benjamin Kozub**, 246 Corbett Avenue, San Francisco, CA 94114. Mr. Kozub started work at Janssen in 2007 where he served as Product Director over Prezista, and Cross-Regional Brand Lead over Intelence, whereby he oversaw the marketing of the drugs. He left Janssen in October 2011. Mr. Kozub is expected to testify in conformity with his deposition testimony. This includes facts regarding: Janssen's marketing and sale of Prezista and Intelence; Prezista's and Intelence's FDA approved and non-approved uses and market segments, and limitations on the drugs' marketability; discussions and meetings regarding how to promote and market the drugs in order to increase their sales; Janssen's consideration of performing trials or studies regarding Intelence once a day dosing, and sales forecasts based on such dosing; Janssen's use of off-label studies; Janssen's tracking of doctors' prescriptions, including speakers; Janssen's tracking of sales, including off-label sales; Janssen's use of marketing research reports; Janssen's use of and tracking of Medical Information Request forms; Janssen's use and implementation of the Speaker Program; Janssen's marketing efforts aimed toward institutions; Return on Investment analyses regarding the Speaker Program; and Janssen's use and implementation of Advisory Boards.

15. **Debbie Kenworthy**, 1125 Trenton Harbourton Road, Titusville, NJ. Ms. Kenworthy started work at Janssen in 2010. From 2010 to 2015, she worked in Insight and Analytics, which involved marketing research, sales, and forecasting. Ms. Kenworthy is expected to testify in conformity with her deposition testimony. This includes facts regarding: Janssen's marketing and sale of Prezista and Intelence; Prezista's and Intelence's FDA approved and non-approved uses; discussions and meetings regarding how to promote and market the drugs in order to increase their sales; Janssen's tracking of sales and doctors' prescriptions, including off-label sales and prescriptions; Janssen's marketing and field surveys and research used to guide Janssen's marketing messages and aid the sales representatives; Janssen's use of marketing research reports; Janssen's use of and tracking of Medical Information Request forms.

16. **Catherine Kaucher**, 246 Pierce Street, Philadelphia, PA 19148. In 2006, Ms. Kaucher worked in the Compliance Department as an Oversight and Monitoring Analyst. She then served as the Compliance Officer from 2011 to 2015. Ms. Kaucher is expected to testify in conformity with her deposition testimony. This includes facts regarding: Janssen's marketing and sale of Prezista and Intelence; the Compliance Department's policies and responsibilities regarding Janssen's promotion and sale of Prezista and Intelence, Janssen's Speaker Program, Janssen's use of Advisory Boards, and Janssen's use of Medical Request Forms; Compliance's responsibility over inquiries, audits, and investigations; Janssen's Corporate Integrity Agreements and their requirements.

17. **Russell Moyer**, Pelham, New Hampshire. Mr. Moyer served as a sales representative who sold Prezista and Intelence to doctors in states located in the New England District. He is expected to testify about Prezista's and Intelence's FDA approved uses and indications, and limited marketability; senior

personnel's efforts and directives given to Janssen employees aimed toward increasing sales of these drugs; Janssen's pressure on sales representatives to meet their sales goals; Janssen's marketing of these drugs through sales calls; Janssen's use of off-label studies regarding these drugs; Janssen's use of and tracking of Medical Information Request forms; the tracking of doctors' prescriptions before and after sales calls and paid speeches; Janssen's use of Return on Investment analyses; Janssen's use and implementation of the Speaker Program; the practice of not committing improper practices to writing; and Janssen's submission of false claims for reimbursement to insurance programs funded by the United States which were ineligible for reimbursement.

18. **Juan Bailey**, Mount Sinai Downtown Union Square Infectious Diseases, 10 Union Square East, New York City, New York 10003. Dr. Bailey was a doctor who prescribed Prezista and Intelence, and he was paid by Janssen to serve on its Speaker Program. He is expected to testify about Janssen's marketing of Prezista and Intelence; Janssen's use and implementation of its Speaker Program, including the manner in which Janssen trained and coached speakers to speak about the drugs, the conditions imposed for serving on the Program and remaining on it, and the fact that he was removed from the Speaker program and the reasons given to him, as well as his understanding of why he was dismissed from the program.

19. Custodian of Records of Advance Health Media, LLC. He or she is expected to testify about the documents that were produced in this litigation, the location and collection of those documents, and the authenticity of the documents.

20. Custodian of Records of MedForce, Inc. He or she is expected to testify about the documents that were produced in this litigation, the location and collection of those documents, and the authenticity of the documents.

21. Custodian of Records of Partners in Loyalty Marketing, Inc. He or she is expected to testify about the documents that were produced in this litigation, the location and collection of those documents, and the authenticity of the documents.

22. Custodian of Records of Centers for Medicare & Medicaid Services ("CMS"). He or she is expected to testify about the documents that were produced in this litigation, the location and collection of those documents, and the authenticity of the documents.

23. Custodian of Records of The AIDS Drug Program ("ADAP"). He or she is expected to testify about the documents that were produced in this litigation, the location and collection of those documents, and the authenticity of the documents.

24. Custodian of Records of Rite Aid Corp. He or she is expected to testify about the documents that were produced in this litigation, the location and collection of those documents, and the authenticity of the documents.

25. Custodian of Records of Walgreen Co. He or she is expected to testify about the

documents that were produced in this litigation, the location and collection of those documents, and the authenticity of the documents.

26. Custodian of Records of BioScrip, Inc. He or she is expected to testify about the documents that were produced in this litigation, the location and collection of those documents, and the authenticity of the documents.

27. Custodian of Records of the U.S Food and Drug Administration. He or she is expected to testify about the documents that were produced in this litigation, the location and collection of those documents, and the authenticity of the documents.

28. Custodian of Records of The Division of Drug Marketing, Advertising and Communications ("DDMAC") and/or its successor, the Office of Prescription Drug Promotion. He or she is expected to testify about the documents that were produced in this litigation, the location and collection of those documents, and the authenticity of the documents.

29. Custodian of Records of the Department of Justice. He or she is expected to testify about the documents that were produced in this litigation, the location and collection of those documents, and the authenticity of the documents.

30. Custodian of Records of ZS Associates. He or she is expected to testify about the documents that were produced in this litigation, the location and collection of those documents, and the authenticity of the documents.

31. Janssen's corporate representative. He or she is expected to testify about facts regarding: Janssen's marketing and sale of Prezista and Intelence; how Prezista was Janssen's first HIV drug on the market; Prezista's and Intelence's FDA approved uses and indications, which limited the drugs' marketability and sales; Prezista's sales being below forecasts after its launch; discussions and meetings among senior executives and others regarding the drugs' uses and unapproved off-label uses, and how to promote and market the drugs in order to increase their sales; Janssen's expectations, monitoring, and evaluations of sales representatives regarding sales; Janssen's tracking of doctors' prescriptions, including speakers' prescriptions; Janssen's use of and tracking of Medical Information Request forms; the use of marketing research reports and their findings; Janssen's tracking of sales, including off-label sales; Janssen's use and implementation of the Speaker Program which caused an increase in paid speakers' and attendees' prescriptions; Janssen's use and implementation of Advisory Boards; Janssen's analysis of Return on Investment relating to its Speaker Program; Janssen's Corporate Integrity Agreements and Certificates of Compliance; and the submission of claims to Government Health Care Programs. S/he will also testify about the authenticity of Janssen's documents.

B. On damages, Relators intend to call the following fact witnesses who will testify in accordance with the following summaries:

1. **Mark Wilhelm**, 24954 North Turkey Creek Road, Evergreen, CO 80439. Mr. Wilhelm is expected to testify in conformity with his deposition testimony. This

includes the facts that Janssen's off-label promotion of Prezista and Intelence was a substantial factor in influencing doctors to prescribe the drugs, and it caused an increase in the drugs' sales. Mr. Wilhelm is also expected to testify that Janssen used its Speaker Program as a means to induce doctors to prescribe Prezista and Intelence, including for off-label purposes. The Speaker Program was profitable for Janssen in that it experienced an increase in prescriptions by speakers and attendees. Janssen caused doctors to submit false claims for reimbursement for Prezista and Intelence to Government Health Care Programs.

2. **Sara Strand**, 21 East Huron Street, #805, Chicago, IL 60611. Ms. Strand is expected to testify in conformity with her deposition testimony. This includes the facts that Janssen's off-label promotion of Prezista and Intelence was a substantial factor in influencing doctors to prescribe the drugs, and it caused an increase in the drugs' sales. Ms. Strand is also expected to testify that Janssen used its Speaker Program as a means to induce doctors to prescribe Prezista and Intelence, including for off-label purposes. The Speaker Program was profitable for Janssen in that it experienced an increase in prescriptions by speakers and attendees. When Jansen engaged in the off-label promotion of the drugs to doctors, the doctors then prescribed the drugs to patients covered by Government Health Care Programs.

C. Janssen objects to the following fact witnesses for the reasons stated:

1. **Janssen's objections to Christine Brancaccio:** Janssen objects to Ms. Brancaccio's testimony to the extent that her testimony would include facts outside of her personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Evid. 602 & 701, respectively.

2. **Janssen's objections to Jessica Penelow:** Janssen objects to Ms. Penelow's testimony to the extent that her testimony would include facts outside of her personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Evid. 602 & 701, respectively.

3. **Janssen's objections to Mark Wilhelm:** Janssen objects to Mr. Wilhelm's testimony to the extent that his testimony would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Evid. 602 & 701, respectively.

4. **Janssen's objections to Sara Strand:** Janssen objects to Ms. Strand's testimony to the extent that her testimony would include facts outside of her personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Evid. 602 & 701, respectively.

5. **Janssen's objections to Donna Graham:** Janssen objects to Ms. Graham's testimony to the extent that her testimony would include facts outside of her personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Evid. 602 & 701, respectively.

6. **Janssen's objections to Matthew Grooms:** Janssen objects to Mr. Groom's testimony to the extent that his testimony would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Evid. 602 & 701, respectively.

7. **Janssen's objections to Joseph Holshoe:** Janssen objects to Mr. Holshoe's testimony to the extent that his testimony would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Evid. 602 & 701, respectively.

8. **Janssen's objections to Michael Schiff:** Janssen objects to the extent that Relators' description of Mr. Schiff's expected testimony mischaracterizes Mr. Schiff's prior testimony at his deposition.

9. **Janssen's objections to Michael Iacobellis:** Janssen objects to the extent that Relators' description of Mr. Iacobellis's expected testimony mischaracterizes Mr. Iacobellis's prior testimony at his deposition.

10. **Janssen's objections to Glenn Mattes:** Janssen objects to the extent that Relators' description of Mr. Mattes's expected testimony mischaracterizes Mr. Mattes's prior testimony at his deposition.

11. **Janssen's objections to Mark Gossett:** Janssen objects to the extent that Relators' description of Mr. Gossett's expected testimony mischaracterizes Mr. Gossett's prior testimony at his deposition.

12. **Janssen's objections to Nancy Bartnett:** Janssen objects to the extent that Relators' description of Ms. Bartnett's expected testimony mischaracterizes Ms. Bartnett's prior testimony at her deposition.

13. **Janssen's objections to Anthony Dolisi:** Janssen objects to the extent that Relators' description of Mr. Dolisi's expected testimony mischaracterizes Mr. Dolisi's prior testimony at his deposition.

14. **Janssen's objections to Benjamin Kozub:** Janssen objects to the extent that Relators' description of Mr. Kozub's expected testimony mischaracterizes Mr. Kozub's prior testimony at his deposition.

15. **Janssen's objections to Debbie Kenworthy:** Janssen objects to the extent that Relators' description of Ms. Kenworthy's expected testimony mischaracterizes Ms. Kenworthy's prior testimony at her deposition.

16. **Janssen's objections to Catherine Kaucher:** Janssen objects to the extent that Relators' description of Ms. Kaucher's expected testimony mischaracterizes Ms. Kaucher's prior testimony at her deposition.

17. **Janssen's objections to Russ Moyer:** Janssen objects to Mr. Moyer's testimony to the extent that his testimony would include facts outside of his personal knowledge, or

would offer inadmissible lay opinion testimony. *See* Fed. R. Evid. 602 & 701, respectively.

18. **Janssen's objections to Juan Bailey:** Janssen objects to Dr. Bailey's testimony to the extent that his testimony would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Evid. 602 & 701, respectively.

19. **Janssen's objections to alleged testimony of "Janssen's corporate representative":** Janssen objects to Relators' attempt to call a Rule 30(b)(6) deposition witness as a trial witness. During discovery, Relators noticed a Rule 30(b)(6) deposition and then voluntarily withdrew their notice, waiving their right to seek or use such testimony at trial. "Federal Rule of Civil Procedure 30(b)(6) allows corporate representatives to testify to matters within the corporation's knowledge during deposition, and Rule 32(a)(3) permits an adverse party to use that deposition testimony during trial." *Union Pump Co. v. Centrifugal Tech., Inc*., 404 F. App'x 899, 907-08 (5th Cir. 2010). At trial, "[h]owever, a corporate representative may not testify to matters outside his own personal knowledge 'to the extent that information [is] hearsay not falling within one of the authorized exceptions.'" *Id.*; *see also TIG Ins. Co. v. Tyco Int'l Ltd.*, 919 F. Supp. 2d 439, 454 (M.D. Pa. 2013) ("Although Rule 30(b)(6) allows a corporate designee to testify to matters within the corporation's knowledge during deposition, at trial the designee 'may not testify to matters outside his own knowledge to the extent that information is hearsay not falling within one of the authorized exceptions.'"). Relators may question current and former Janssen employees at trial, including any question regarding authenticity of documents. And, those witnesses will testify based on their personal knowledge. Relators are not, however, entitled to demand the testimony of a Janssen corporate representative at trial, and the Court should preclude Relators from doing so. Additionally, a Janssen corporate representative is not necessary to authenticate documents because Janssen is not objecting to the authenticity of the documents produced from its employees' Janssen files, except for certain documents that were saved to Relators Christine Brancaccio's files and that do not appear to be authentic business records.

20. **Janssen's objections to Mark Wilhelm's damages testimony**: Janssen objects to Mr. Wilhelm testifying regarding damages. Mr. Wilhelm has no personal knowledge to testify regarding any alleged damages to Medicare, Medicaid or ADAP.

21. **Janssen's objections to Sara Strand's damages testimony**: Janssen objects to Ms. Strand testifying regarding damages. Ms. Strand has no personal knowledge to testify regarding any alleged damages to Medicare, Medicaid or ADAP.

7. JANSSEN'S WITNESSES

A. On liability, Janssen intends to call the following fact witnesses who will testify in accordance with the following summaries:

1. **Andre Brutus**. 1 Brookdale Plaza, Brooklyn NY 11212. Dr. Brutus is expected to testify about when, how and why he prescribes Prezista and Intelence to HIV-positive patients. Dr. Brutus also is expected to testify about how Janssen accurately and truthfully promoted Prezista and Intelence, and about Janssen's speaker programs. (Live, live remote, or by trial deposition)

2. **Robert Chavez.** 24 E. 12th Street, New York NY 10003. Dr. Chavez is expected to testify about when, how and why he prescribes Prezista and Intelence to HIV-positive patients. Dr. Chavez also is expected to testify about how Janssen accurately and truthfully promoted Prezista and Intelence, and about Janssen's speaker programs. (Live, live remote, or by trial deposition)

3. **Douglas Cunningham.** 4350 North 19th Ave. Suite 6, Phoenix AZ 85015. Dr. Cunningham is expected to testify about when, how and why he prescribes Prezista and Intelence to HIV-positive patients. Dr. Cunningham also is expected to testify about how Janssen accurately and truthfully promoted Prezista and Intelence, and about Janssen's speaker programs. (Live, live remote, or by trial deposition)

4. **Patrick Dalton.** 54 W. 16th Street APT 98, New York NY 10011. Dr. Dalton is expected to testify about when, how and why he prescribes Prezista and Intelence to HIV-positive patients. Dr. Dalton also is expected to testify about how Janssen accurately and truthfully promoted Prezista and Intelence, and about Janssen's speaker programs. (Live, live remote, or by trial deposition)

5. **Raymond Elliott.** 1111 W Broward Blvd, Fort Lauderdale FL 33312. Dr. Elliott is expected to testify about when, how and why he prescribes Prezista and Intelence to HIV-positive patients. Dr. Elliott also is expected to testify about how Janssen accurately and truthfully promoted Prezista and Intelence, and about Janssen's speaker programs. (Live, live remote, or by trial deposition)

6. **Joe Eron.** 101 Manning Drive, Chapel Hill NC 27514. Dr. Eron is expected to testify about when, how and why he prescribes Prezista and Intelence to HIV-positive patients. Dr. Eron ialso expected to testify about how Janssen accurately and truthfully promoted Prezista and Intelence, and about Janssen's speaker programs. (Live, live remote, or by trial deposition)

7. **Ian Frank.** 210 S. 25th Street, Unit 405, Philadelphia PA 19103. Dr. Frank is expected to testify about when, how and why he prescribes Prezista and Intelence to HIV-positive patients. Dr. Frank also is expected to testify about how Janssen accurately and truthfully promoted Prezista and Intelence, and about Janssen's speaker programs. (Live, live remote, or by trial deposition)

8. **Jeffrey Green.** 71 Bristol Dr., Boynton Beach FL 33436. Dr. Green is expected to testify about when, how and why he prescribes Prezista and Intelence to HIV-positive patients. Dr. Green also is expected to testify about how Janssen accurately and truthfully promoted Prezista and Intelence, and about Janssen's speaker programs. (Live, live remote, or by trial deposition)

9. **Ricky Hsu.** 154 W. 14th Street, New York NY 10001. Dr. Hsu is expected to testify about when, how and why he prescribes Prezista and Intelence to HIV-positive patients. Dr. Hsu also is expected to testify about how Janssen accurately and truthfully promoted Prezista and Intelence, and about Janssen's speaker programs. (Live, live remote, or by trial deposition)

10. **Don Kaminsky.** 10 Union Square East, New York NY 10003. Dr. Kaminsky is expected to testify about when, how and why he prescribes Prezista and Intelence to HIV-positive patients. Dr. Kaminsky also is expected to testify about how Janssen accurately and truthfully promoted Prezista and Intelence, and about Janssen's speaker programs. (Live, live remote, or by trial deposition)

11. **Alex McMeeking**. 110 E. 40th Street, New York NY 10016. Dr. McKeeking is expected to testify about when, how and why he prescribes Prezista and Intelence to HIV-positive patients. Dr. McKeeking also is expected to testify about how Janssen accurately and truthfully promoted Prezista and Intelence, and about Janssen's speaker programs. (Live, live remote, or by trial deposition)

12. **Anthony Mills.** 9201 W Sunset Blvd, Ste. 812, Los Angeles CA 90069. Dr. Mills is expected to testify about when, how and why he prescribes Prezista and Intelence to HIV-positive patients. Dr. Mills also is expected to testify about how Janssen accurately and truthfully promoted Prezista and Intelence, and about Janssen's speaker programs.

13. **HarishMoorjani**. 302 Chappaqua Rd, Briarcliff Manor NY 10510. Dr. Moorjani is expected to testify about when, how and why he prescribes Prezista and Intelence to HIV-positive patients. Dr. Moorjani also is expected to testify about how Janssen accurately and truthfully promoted Prezista and Intelence, and about Janssen's speaker programs. (Live, live remote, or by trial deposition)

14. **Frank Palella.** 645 North Michigan Ave. Suite 900, Chicago IL 60611. Dr. Palella is expected to testify about when, how and why he prescribes Prezista and Intelence to HIV-positive patients. Dr. Palella also is expected to testify about how Janssen accurately and truthfully promoted Prezista and Intelence, and about Janssen's speaker programs. (Live, live remote, or by trial deposition)

15. **Elizabeth Race.** 3208 Beverly Drive, Dallas TX 75205. Dr. Race is expected to testify about when, how and why she prescribes Prezista and Intelence to HIV-positive patients. Dr. Race also is expected to testify about how Janssen accurately and

truthfully promoted Prezista and Intelence, and about Janssen's speaker programs. (Live, live remote, or by trial deposition)

16. **Bruce Rashbaum.** 1640 Rhode Island Ave. NW, Suite 800, Washington DC 20036. Dr. Rashbaum is expected to testify about when, how and why he prescribes Prezista and Intelence to HIV-positive patients. Dr. Rashbaum also is expected to testify about how Janssen accurately and truthfully promoted Prezista and Intelence, and about Janssen's speaker programs. (Live, live remote, or by trial deposition)

17. **David Rubin.** 138-47 Horace Harding Expressway, 2nd FL, Queens NY 11367. Dr. Rubin is expected to testify about when, how and why he prescribes Prezista and Intelence to HIV-positive patients. Dr. Rubin also is expected to testify about how Janssen accurately and truthfully promoted Prezista and Intelence, and about Janssen's speaker programs. (Live, live remote, or by trial deposition)

18. **Nadim Salomon.** 317 E. 17th Street, New York NY 10003. Dr. Salomon is expected to testify about when, how and why he prescribes Prezista and Intelence to HIV-positive patients. Dr. Salomon also is expected to testify about how Janssen accurately and truthfully promoted Prezista and Intelence, and about Janssen's speaker programs. (Live, live remote, or by trial deposition)

19. **Shannon Schrader.** 4101 Greenbriar, Suite 200, Houston TX 77098. Dr. Schrader is expected to testify about when, how and why she prescribes Prezista and Intelence to HIV-positive patients. Dr. Schrader also is expected to testify about how Janssen accurately and truthfully promoted Prezista and Intelence, and abuot Janssen's speaker programs. (Live, live remote, or by trial deposition)

20. **Sorona Segal-Mauer.** 138-47 Horace Harding Expressway, 2nd FL, Queens NY 11367. Dr. Segal-Mauer is expected to testify about when, how and why she prescribes Prezista and Intelence to HIV-positive patients. Dr. Segal-Mauer also is expected to testify about how Janssen accurately and truthfully promoted Prezista and Intelence, and about Janssen's speaker programs. (Live, live remote, or by trial deposition)

21. **Michael Sension.** 1101 NW 1st Street, Ft. Lauderdale FL 33311. Dr. Sension is expected to testify about when, how and why he prescribes Prezista and Intelence to HIV-positive patients. Dr. Sension also is expected to testify about how Janssen accurately and truthfully promoted Prezista and Intelence, and about Janssen's speaker programs. (Live, live remote, or by trial deposition)

22. **Stanley Yancovitz**. 5900 Arlington Avenue, Apt. 9U, Bronx NY 10471. Dr. Yancovitz is expected to testify about when, how and why he prescribes Prezista and Intelence to HIV-positive patients. Dr. Yancovitz also is expected to testify about how Janssen accurately and truthfully promoted Prezista and Intelence, and about Janssen's speaker programs. (Live, live remote, or by trial deposition)

23. **Kathy Aratoon.** 8268 164th Street, Queens NY 11432. Ms. Aratoon is expected to testify about when, how and why she prescribes Prezista and Intelence to HIV-positive patients. Ms. Aratoon also is expected to testify about how Janssen accurately and truthfully promoted Prezista and Intelence, and about Janssen's speaker programs. (Live, live remote, or by trial deposition)

24. **Abby Freedberg.** 31 Washington Sq FL 4, New York NY 10011. Ms. Freedberg is expected to testify about when, how and why she prescribes Prezista and Intelence to HIV-positive patients. Dr. Freedberg also is expected to testify about how Janssen accurately and truthfully promoted Prezista and Intelence, and about Janssen's speaker programs. (Live, live remote, or by trial deposition)

25. **Rita Kelly.** 205 Belle Mead Ave, East Setauket NY 11733. Ms. Kelly is expected to testify about when, how and why she prescribes Prezista and Intelence to HIV-positive patients. Ms. Kelly also is expected to testify about how Janssen accurately and truthfully promoted Prezista and Intelence, and about Janssen's speaker programs. (Live, live remote, or by trial deposition)

26. **Mark Miller.** 275 7th Ave., 12th Floor, New York NY 10011. Mr. Miller is expected to testify about when, how and why he prescribes Prezista and Intelence to HIV-positive patients. Ms. Miller also is expected to testify about how Janssen accurately and truthfully promoted Prezista and Intelence, and about Janssen's speaker programs. (Live, live remote, or by trial deposition)

27. **Linda Ording-Bauer.** 205 Belle Mead Ave, East Setauket NY 11733. Ms. Ording-Bauer is expected to testify about when, how and why she prescribes Prezista and Intelence to HIV-positive patients. Ms. Ording-Bauer also is expected to testify about how Janssen accurately and truthfully promoted Prezista and Intelence, and about Janssen's speaker programs. (Live, live remote, or by trial deposition)

28. **Karen Weisz.** 3330 Noyac Rd BLDG A, Sag Harbor NY 11963. Ms. Weisz is expected to testify about when, how and why she prescribes Prezista and Intelence to HIV-positive patients. Ms. Weisz also is expected to testify about how Janssen accurately and truthfully promoted Prezista and Intelence, and about Janssen's speaker programs. (Live, live remote, or by trial deposition)

29. **Michael Daly.** 1215 Waverly Walk, Philadelphia PA 19147. Mr. Daly is expected to testify regarding his role and responsibilities in Janssen's Marketing department, including how Marketing developed promotional messages and oversaw Janssen's various speaker programs. Mr. Daly is further expected to testify regarding how Marketing worked with other Janssen departments to accurately and truthfully market Prezista and Intelence and to properly use speaker programs. (Live)

30. **Jason Kenig.** Johnson & Johnson, 1 Johnson And Johnson Plaza, New Brunswick NJ 08933. Mr. Kenig is expected to testify regarding his role and responsibilities in Janssen's Marketing department, including how Marketing developed promotional

messages and oversaw Janssen's various speaker programs. Mr. Kenig is further expected to testify regarding how Marketing worked with other Janssen departments to accurately and truthfully market Prezista and Intelence and to properly use speaker programs. (Live)

31. **Ben Kozub.** 246 Corbett Ave, San Francisco CA 94114. Mr. Kozub is expected to testify regarding his role and responsibilities in Janssen's Marketing department, including how Marketing developed promotional messages and oversaw Janssen's various speaker programs. Mr. Kozub is further expected to testify regarding how Marketing worked with other Janssen departments to accurately and truthfully market Prezista and Intelence and to properly use speaker programs. (Live)

32. **Maureen Kushmore.** Johnson & Johnson, 1 Johnson And Johnson Plaza, New Brunswick NJ 08933. Ms. Kushmore is expected to testify regarding her role and responsibilities in Janssen's Marketing department, including how Marketing developed promotional messages and oversaw Janssen's various speaker programs. Ms. Kushmore is further expected to testify regarding how Marketing worked with other Janssen departments to accurately and truthfully market Prezista and Intelence and to properly use speaker programs. (Live)

33. **Candice Long.** Johnson & Johnson, 1 Johnson And Johnson Plaza, New Brunswick NJ 08933. Ms. Long is expected to testify regarding her role and responsibilities in Janssen's Marketing department, including how Marketing developed promotional messages and oversaw Janssen's various speaker programs. Ms. Long is further expected to testify regarding how Marketing worked with other Janssen departments to accurately and truthfully market Prezista and Intelence and to properly use speaker programs. (Live)

34. **Kim Saladana**. Ms. Saladana currently resides in Canada. Ms. Saladana is expected to testify regarding her role and responsibilities in Janssen's Marketing department, including how Marketing developed promotional messages and oversaw Janssen's various speaker programs. Ms. Saladana is further expected to testify regarding how Marketing worked with other Janssen departments to accurately and truthfully market Prezista and Intelence and to properly use speaker programs. (Live, live remote, or by trial deposition)

35. **Seham (Se-Se) Yennes.** 34 Winding Way, Princeton NJ 08540. Ms. Yennes is expected to testify regarding her role and responsibilities in Janssen's Marketing department, including how Marketing developed promotional messages and oversaw Janssen's various speaker programs. Ms. Yennes is further expected to testify regarding how Marketing worked with other Janssen departments to accurately and truthfully market Prezista and Intelence and to properly use speaker programs. (Live, live remote, or by trial deposition)

36. **Ron Falcon.** 83 Quakertown Rd, Pittstown NJ 08867. Dr. Falcon is expected to testify regarding his role and responsibilities in Janssen's Marketing and Medical departments.

Dr. Falcon is expected to testify regarding how Marketing developed promotional messages, oversaw Janssen's various speaker programs, and worked with other Janssen departments to accurately and truthfully market Prezista and Intelence and to properly use speaker programs. Dr. Falcon is further expected to testify about how the Medical department reviewed proposed promotional messages and materials, and worked with other Janssen departments to accurately and truthfully market Prezista and Intelence." (Live)

37. **Alexia Burnett Salinas.** Johnson & Johnson, 1 Johnson And Johnson Plaza, New Brunswick NJ 08933. Ms. Burnett Salinas is expected to testify regarding her role and responsibilities in Janssen's Sales and Marketing departments. Ms. Burnett Salinas is expected to testify about how Sales accurately and truthfully promoted Prezista and Intelence to doctors and other healthcare providers. Ms. Burnett Salinas is further expected to testify that she was instructed (and instructed others) to accurately and truthfully promote Prezista and Intelence. She also is expected to testify that the Sales department properly used speaker programs to market Prezista and Intelence to speaker program attendees and to educate those attendees about HIV treatment options, including Prezista and Intelence. Ms. Burnett Salinas also is expected to testify regarding how Marketing developed promotional messages, oversaw Janssen's various speaker programs, and worked with other Janssen departments to accurately and truthfully market Prezista and Intelence and to properly use speaker programs. (Live)

38. **Brian Baugh.** Johnson & Johnson, 1 Johnson And Johnson Plaza, New Brunswick NJ 08933. Dr. Baugh is expected to testify regarding his role and responsibilities in Janssen's Medical department, including how the Medical department reviewed proposed promotional messages and materials. Dr. Baugh is further expected to testify regarding how Medical worked with other Janssen departments to accurately and truthfully market Prezista and Intelence. (Live)

39. **Guy De La Rosa.** 538 Shoemaker Dr., Fountainville PA 18923. Dr. De La Rosa is expected to testify regarding his role and responsibilities in Janssen's Medical department, including how the Medical department reviewed proposed promotional messages and materials. Dr. De La Rosa is further expected to testify regarding how Medical worked with other Janssen departments to accurately and truthfully market Prezista and Intelence. (Live)

40. **Jim Witek.** 7412 Ferry Rd., New Hope PA 18938. Dr. Witek is expected to testify regarding his role and responsibilities in Janssen's Medical department, including how the Medical department reviewed proposed promotional messages and materials. Dr. Witek is further expected to testify regarding how Medical worked with other Janssen departments to accurately and truthfully market Prezista and Intelence. (Live)

41. **Michael Iacobellis.** Johnson & Johnson, 1 Johnson And Johnson Plaza, New Brunswick NJ 08933. Mr. Iacobellis is expected to testify regarding his role and responsibilites in Janssen's Sales department, including how Sales accurately and truthfully marketed Prezista and Intelence to doctors and other healthcare providers.

Mr. Iacobellis is further expected to testify that he was instructed (and instructed others) to accurately and truthfully promote Prezista and Intelence. Mr. Iacobellis also is expected to testify that the Sales department properly used speaker programs to market Prezista and Intelence to speaker program attendees and to educate those attendees about HIV treatment options, including Prezista and Intelence. (Live)

42. **Timothy McSherry.** Johnson & Johnson, 1 Johnson And Johnson Plaza, New Brunswick NJ 08933. Mr. McSherry is expected to testify regarding his role and responsibilities in Janssen's Sales Department, including how Sales accurately and truthfully promoted Prezista and Intelence to doctors and other healthcare providers. Mr. McSherry is further expected to testify that he was instructed (and instructed others) to accurately and truthfully promote Prezista and Intelence. Mr. McSherry also is expected to testify that the Sales department properly used speaker programs to market Prezista and Intelence to speaker program attendees and to educate those attendees about HIV treatment options, including Prezista and Intelence. (Live)

43. **Nancy Bartnett.** Johnson & Johnson, 1 Johnson And Johnson Plaza, New Brunswick NJ 08933. Ms. Bartnett is expected to testify regarding her role and responsibilities in Janssen's Sales department, including how Sales accurately and truthfully promoted Prezista and Intelence to doctors and other healthcare providers. Ms. Bartnett is further expected to testify that she was instructed (and instructed others) to accurately and truthfully promote Prezista and Intelence. Ms. Bartnett also is expected to testify that the Sales department properly used speaker programs to market Prezista and Intelence to speaker program attendees and to educate those attendees about HIV treatment options, including Prezista and Intelence. (Live)

44. **Anthony Dolisi.** Reed Smith, Three Logan Square, 1717 Arch Street, Suite 3100, Philadelphia PA 19103. Mr. Dolisi is expected to testify regarding his role and responsibilities in Janssen's Sales department, including how Sales accurately and truthfully promoted Prezista and Intelence to doctors and other healthcare providers. Mr. Dolisi is further expected to testify that he was instructed (and instructed others) to accurately and truthfully promote Prezista and Intelence.Mr. Dolisi also is expected to testify that the Sales department properly used speaker programs to market Prezista and Intelence to speaker program attendees and to educate those attendees about HIV treatment options, including Prezista and Intelence. (Live)

45. **Scott Libby.** Johnson & Johnson, 1 Johnson And Johnson Plaza, New Brunswick NJ 08933. Mr. Libby is expected to testify regarding his role and responsibilities in Janssen's Sales department, including how Sales accurately and truthfully promoted Prezista and Intelence to doctors and healthcare providers. Mr. Libby is further expected to testify that he was instructed (and instructed others) to accurately and truthfully promote Prezista and Intelence. Mr. Libby also is expected to testify that the Sales department properly used speaker programs to market Prezista and Intelence to speaker program attendees and to educate those attendees about HIV treatment options, including Prezista and Intelence. (Live)

46. **Ronald Martin.** 8 Pleasant Ave., Lincoln Park NJ 07035. Mr. Martin is expected to testify regarding his role and responsibilities in Janssen's Sales department, including how Sales accurately and truthfully promoted Prezista and Intelence to doctors and other healthcare providers. Mr. Martin is further expected to testify regarding how he trained sales representatives and others in the Sales department to accurately and truthfully promote Prezista and Intelence. (Live)

47. **Deb O'Connor.** 213 Neptune Place, Sea Girt NJ 08750. Ms. O'Connor is expected to testify regarding her role and responsibilites in Janssen's Sales department, including how Sales accurately and truthfully marketed Prezista and Intelence to doctors and other healthcare providers. Ms. O'Connor is further expected to testify that she was instructed (and instructed others) to accurately and truthfully promote Prezista and Intelence. Ms. O'Connor also is expected to testify that the Sales department properly used speaker programs to market Prezista and Intelence to speaker program attendees and to educate those attendees about HIV treatment options, including Prezista and Intelence. (Live)

48. **Bill Whyte.** Johnson & Johnson, 1 Johnson And Johnson Plaza, New Brunswick NJ 08933. Mr. Whyte is expected to testify regarding his role and responsibilites in Janssen's Sales department, including how Sales accurately and truthfully marketed Prezista and Intelence to doctors and other healthcare providers. Mr. Whyte is further expected to testify that he was instructed (and instructed others) to accurately and truthfully promote Prezista and Intelence. Mr. Whyte also is expected to testify that the Sales department properly used speaker programs to market Prezista and Intelence to speaker program attendees and to educate those attendees about HIV treatment options, including Prezista and Intelence. (Live)

49. **Doyletta Minix.** Johnson & Johnson, 1 Johnson And Johnson Plaza, New Brunswick NJ 08933. Ms. Minix is expected to testify regarding her role and responsibilities in Janssen's Sales department, including how Sales accurately and truthfully promoted Prezista and Intelence to doctors and other healthcare providers. Ms. Minix is further expected to testify that she was instructed (and instructed others) to accurately and truthfully promote Prezista and Intelence. Ms. Minix also is expected to testify that the Sales department properly used speaker programs to market Prezista and Intelence to speaker program attendees and to educate those attendees about HIV treatment options, including Prezista and Intelence. (Live)

50. **Nancy Peterson.** 95 W River Road W., Rumson NJ 07760. Ms. Peterson is expected to testify regarding her role and responsibilities in Janssen's Sales department, including how Sales accurately and truthfully promoted Prezista and Intelence to doctors and other healthcare providers. Ms. Peterson is further expected to testify that she was instructed (and instructed others) to accurately and truthfully promote Prezista and Intelence. Ms. Peterson also is expected to testify that the Sales department properly used speaker programs to market Prezista and Intelence to speaker program attendees and to educate those attendees about HIV treatment options, including Prezista and Intelence. (Live)

51. **Eric Sherr.** 46 Lambert Rd, Cross River NJ 10518. Mr. Sherr is expected to testify regarding his role and responsibilities in Janssen's Sales department, including how Sales accurately and truthfully promoted Prezista and Intelence to doctors and other healthcare providers. Mr. Sherr also is expected to testify that the Sales department properly used speaker programs to market Prezista and Intelence to speaker program attendees and to educate those attendees about HIV treatment options, including Prezista and Intelence. (Live)

52. **Vicky O'Reilly.** Johnson & Johnson, 1 Johnson And Johnson Plaza, New Brunswick NJ 08933. Ms. O'Reilly is expected to testify regarding her role and responsibilities in Janssen's Business Analytics department, including how Business Analytics studied the HIV market to develop business plans and forecasts, and to support other Janssen departments. (Live)

53. **Gregg Ruppersberger.** 1385 Colony Way, Yardley PA 19067. Mr. Ruppersberger is expected to testify regarding his role and responsibilities in Janssen's Business Analytics department, including how Business Analytics studied the HIV market to develop business plans and forecasts, and to support other Janssen departments. (Live)

54. **Debbie Kenworthy.** Johnson & Johnson, 1 Johnson And Johnson Plaza, New Brunswick NJ 08933. Ms. Kenworthy is expected to testify regarding her role and responsibilities in Janssen's Business Analytics department, including how Business Analytics studied the HIV market to develop business plans and forecasts, and to support other Janssen departments. (Live)

55. **Mike Driscoll.** Johnson & Johnson, 1 Johnson And Johnson Plaza, New Brunswick NJ 08933. Mr. Driscoll is expected to testify regarding his role and responsibilities in Compliance, including how Compliance monitored whether Janssen's efforts to market Prezista and Intelence directly to healthcare providers and to properly use speaker programs complied with company policies. Mr. Driscoll also is expected to testify about how Compliance worked with and supported other Janssen departments. (Live)

56. **Catherine Kaucher.** Johnson & Johnson, 1 Johnson And Johnson Plaza, New Brunswick NJ 08933. Ms. Kaucher is expected to testify regarding her role and responsibilities in Compliance, including how Compliance monitored whether Janssen's efforts to market Prezista and Intelence directly to healthcare providers and to properly use speaker programs complied with company policies. Ms. Kaucher also is expected to testify about how Compliance worked with and supported other Janssen departments. (Live)

57. **Erin Parsons.** Johnson & Johnson, 1 Johnson And Johnson Plaza, New Brunswick NJ 08933. Ms. Parsons is expected to testify regarding her role and responsibilities in Compliance, including how Compliance monitored whether Janssen's efforts to market Prezista and Intelence directly to healthcare providers complied with company policies. Ms. Parsons also is expected to testify about how Compliance worked with and supported other Janssen departments. (Live)

58. **Amit Patel.** 16755 Coyote Drive, #10, San Diego CA 92127. Mr. Patel is expected to testify regarding his role and responsibilities in Compliance, including how Compliance monitored whether Janssen's efforts to market Prezista and Intelence directly to healthcare providers and to properly use speaker programs complied with company policies. Mr. Patel also is expected to testify about how Compliance worked with and supported other Janssen departments. (Live, live remote, or by trial deposition)

59. **Michael Schiff.** Douglas Conover, 1901 South Calumet Avenue, No. 1406, Chicago IL 60616. Mr. Schiff is expected to testify about the work he performed for Janssen to evaluate Janssen's consumer and physician marketing programs regarding Prezista, Intelence and HIV. (Live, live remote, or by trial deposition)

60. **Mark Gossett.** 316 Valdez Ave, Half Moon Bay CA 94019. Mr. Gossett is expected to testify regarding his role and responsibilities as the Vice President of Janssen's HIV business, including how Janssen accurately and truthfully marketed Prezista and Intelence to doctors and other healthcare providers, and properly used speaker programs. (Live, live remote, or by trial deposition)

61. **Glenn Mattes.** 4524 Everview Drive, Doylestown PA 18902. Mr. Mattes is expected to testify regarding his role and responsibilities as the President of Janssen's HIV business, including how Janssen accurately and truthfully marketed Prezista and Intelence to doctors and other healthcare providers, and properly used speaker programs. (Live)

62. **H. Clifford Lane.** Paul Robertson, Office of the General Counsel, Public Health Division, NIH Branch, 31 Center Drive - Bldg. 31, Room 2B-50, Bethesda MD 20892. Dr. Lane (a voting member and Co-Chair of the Department of Health and Human Services Panel on Antiretroviral Guidelines for Adults and adolescents, a working group of the Office of AIDS Research Advisory Council (the "Panel")) is expected to testify regarding how the Panel evaluates, considers and recommends HIV treatments cited in the Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV (the "Guidelines"), and (in some instances) makes specific treatment recommendations. Dr. Lane also is expected to testify that the Guidelines reflect the federal government's position on the standard of care for HIV treatment. (Live, live remote, or by trial deposition)

63. **B. Kaye Hayes.** Anna Jagelewski, Office of the General Counsel, Public Health Division, Public Health and Science Branch, U.S. Department of Health and Human Services, 200 Independence Avenue, SW, Washington DC 20201. Ms. Hayes (the Executive Director and Designated Federal Officer for the Presidential Advisory Council on HIV/AIDS ("PACHA")) is expected to testify regarding the National HIV/AIDS Strategy ("NHAS") and how PACHA monitors implementation of the NHAS. Ms. Hayes also is expected to testify about PACHA's recommendations "to ensure that all HIV care providers have the knowledge and training to provide quality HIV care consistent with the latest [HHS] treatment guidelines," and to ensure open access to, and reimbursement of, HIV medications for HIV-positive patients. (Live, live remote, or by trial deposition)

64. **Cal Cohen.** 17125 Avenue Le Rivage, Boca Raton FL 33496. Dr. Cohen is expected to testify about when, how and why he prescribes Prezista and Intelence to HIV-positive patients. Dr. Cohen also is expected to testify about how Janssen accurately and truthfully promoted Prezista and Intelence, and about Janssen's speaker programs. (Live, live remote, or by trial deposition)

65. **Juan Bailey.** 317 E. 17th Street, New York NY 10003. Dr. Bailey is expected to testify about when, how and why he prescribes Prezista and Intelence to HIV-positive patients. Dr. Bailey also is expected to testify about how Janssen accurately and truthfully promoted Prezista and Intelence, and about Janssen's speaker programs. (Live, live remote, or by trial deposition)

B. Relators object to the following fact witnesses for the reasons stated:

1. **Relators' objections to Andre Brutus**: Relators object to Dr. Brutus' testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further object that Janssen did not provide a sufficient description of his expected testimony herein.

2. **Relators' objections to Robert Chavez**: Relators object to Dr. Chavez's testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further object that Janssen did not provide a sufficient description of his expected testimony herein.

3. **Relators' objections to Douglas Cunningham**: Relators object to Dr. Cunningham's testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further object that Janssen did not provide a sufficient description of his expected testimony herein.

4. **Relators' objections to Patrick Dalton**: Relators object to Dr. Dalton's testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further object that Janssen did not provide a sufficient description of his expected testimony herein.

5. **Relators' objections to Raymond Elliott**: Relators object to Dr. Elliott's testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further object that Janssen did not provide a sufficient description of his expected testimony herein.

6. **Relators' objections to Joe Eron**: Relators object to Dr. Eron's testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further object that Janssen did not provide a sufficient description of his expected testimony herein.

7. **Relators' objections to Ian Frank**: Relators object to Dr. Frank's testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further object that Janssen did not provide a sufficient description of his expected testimony herein.

8. **Relators' objections to Jeffrey Green**: Relators object to Dr. Green's testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further object that Janssen did not provide a sufficient description of his expected testimony herein.

9. **Relators' objections to Ricky Hsu**: Relators object to Dr. Hsu's testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further object that Janssen did not provide a sufficient description of his expected testimony herein.

10. **Relators' objections to Don Kaminsky**: Relators object to Dr. Kaminsky's testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further object that Janssen did not provide a sufficient description of his expected testimony herein.

11. **Relators' objections to Alex McMeeking**: Relators object to Dr. McMeeking's testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further object that Janssen did not provide a sufficient description of his expected testimony herein.

12. **Relators' objections to Anthony Mills**: Relators object to Dr. Mills' testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further object that Janssen did not provide a sufficient description of his expected testimony herein.

13. **Relators' objections to Harish Moorjani**: Relators object to Dr. Moorjani's testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further object that Janssen did not provide a sufficient description of his expected testimony herein.

14. **Relators' objections to Frank Palella**: Relators object to Dr. Palella's testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further that Janssen did not provide a sufficient description of his expected testimony herein

15. **Relators' objections to Elizabeth Race**: Relators object to Dr. Race's testimony to the extent that it would include facts outside of her personal knowledge, or would offer

inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further object that Janssen did not provide a sufficient description of her expected testimony herein.

16. **Relators' objections to Bruce Rashbaum**: Relators object to Dr. Rashbaum's testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further object that Janssen did not provide a sufficient description of his expected testimony herein.

17. **Relators' objections to David Rubin**: Relators object to Dr. Rubin's testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further object that Janssen did not provide a sufficient description of his expected testimony herein.

18. **Relators' objections to Nadim Salomon**: Relators object to Dr. Salomon's testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further object that Janssen did not provide a sufficient description of his expected testimony herein.

19. **Relators' objections to Shannon Schrader**: Relators object to Dr. Schrader's testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further object that Janssen did not provide a sufficient description of his expected testimony herein.

20. **Relators' objections to Sorona Segal-Maurer**: Relators object to Dr. Segal-Maurer's testimony to the extent that it would include facts outside of her personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further object that Janssen did not provide a sufficient description of her expected testimony herein.

21. **Relators' objections to Michael Sension**: Relators object to Dr. Sension's testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further object that Janssen did not provide a sufficient description of his expected testimony herein.

22. **Relators' objections to Stanley Yancovitz**: Relators object to Dr. Yancovtiz's testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further object that Janssen did not provide a sufficient description of his expected testimony herein.

23. **Relators' objections to Kathy Aratoon**: Relators object to Ms. Aratoon's testimony to the extent that it would include facts outside of her personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further object that Janssen did not provide a sufficient description of her

expected testimony herein.

24. **Relators' objections to Abbe Friedberg**: Relators object to Ms. Friedberg's testimony to the extent that it would include facts outside of her personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further object that Janssen did not provide a sufficient description of her expected testimony herein.

25. **Relators' objections to Rita Kelly**: Relators object to Ms. Kelly's testimony to the extent that it would include facts outside of her personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further object that Janssen did not provide a sufficient description of her expected testimony herein.

26. **Relators' objections to Mark Miller**: Relators object to Mr. Miller's testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further object that Janssen did not provide a sufficient description of his expected testimony herein.

27. **Relators' objections to Linda Ording-Bauer**: Relators object to Ms. Ording-Bauer's testimony to the extent that it would include facts outside of her personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further object that Janssen did not provide a sufficient description of her expected testimony herein.

28. **Relators' objections to Karen Weisz**: Relators object to Ms. Weisz's testimony to the extent that it would include facts outside of her personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further object that Janssen did not provide a sufficient description of her expected testimony herein.

29. **Relators' objections to Michael Daly**: Relators object to Mr. Daly's testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively.

30. **Relators' objections to Jason Kenig**: Relators object to Mr. Kenig's testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively.

31. **Relators' objections to Ben Kozub**: Relators object to Mr. Kozub's testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively.

32. **Relators' objections to Maureen Kushmore**: Relators object to Ms. Kushmore's testimony to the extent that it would include facts outside of her personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively.

33. **Relators' objections to Candice Long**: Relators object to Ms. Long's testimony to the

extent that it would include facts outside of her personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively.

34. **Relators' objections to Kim Saladana**: Relators object to Ms. Saladana's testimony to the extent that it would include facts outside of her personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively.

35. **Relators' objections to Seham (Se-Se) Yennes**: Relators object to Ms. Yennes' testimony to the extent that it would include facts outside of her personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further object that Janssen did not provide a sufficient description of her expected testimony herein.

36. **Relators' objections to Ron Falcon**: Relators object to Dr. Falcon's testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further object that Janssen did not provide a sufficient description of his expected testimony herein.

37. **Relators' objections to Alexia Burnett Salinas**: Relators object to Ms. Burnett Salinas' testimony to the extent that it would include facts outside of her personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further object that Janssen did not provide a sufficient description of her expected testimony herein.

38. **Relators' objections to Brian Baugh**: Relators object to Dr. Baugh's testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively.

39. **Relators' objections to Guy De La Rosa**: Relators object to Dr. De La Rosa's testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further that Janssen did not provide a sufficient description of his expected testimony herein.

40. **Relators' objections to Jim Witek**: Relators object to Dr. Witek's testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further object that Janssen did not provide a sufficient description of his expected testimony herein.

41. **Relators' objections to Michael Iacobellis**: Relators object to Mr. Iacobellis' testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively.

42. **Relators' objections to Timothy McSherry**: Relators object to Mr. McSherry's testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further object that Janssen did not provide a sufficient description

of his expected testimony herein.

43. **Relators' objections to Nancy Bartnett**: Relators object to Ms. Bartnett's testimony to the extent that it would include facts outside of her personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively.

44. **Relators' objections to Anthony Dolisi**: Relators object to Mr. Dolisi's testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively.

45. **Relators' objections to Scott Libby**: Relators object to Mr. Libby's testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further object that Janssen did not provide a sufficient description of his expected testimony herein.

46. **Relators' objections to Ronald Martin**: Relators object to Mr. Martin's testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively.

47. **Relators' objections to Deb O'Connor**: Relators object to Ms. O'Connor's testimony to the extent that it would include facts outside of her personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further object that Janssen did not provide a sufficient description of her expected testimony herein.

48. **Relators' objections to Bill Whyte**: Relators object to Mr. Whyte's testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively.

49. **Relators' objections to Doyletta Minix**: Relators object to Ms. Minix's testimony to the extent that it would include facts outside of her personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further object that Janssen did not provide a sufficient description of her expected testimony herein.

50. **Relators' objections to Nancy Peterson**: Relators object to Ms. Peterson's testimony to the extent that it would include facts outside of her personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further object that Janssen did not provide a sufficient description of her expected testimony herein.

51. **Relators' objections to Eric Sherr**: Relators object to Mr. Sherr's testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively.

52. **Relators' objections to Vicky O'Reilly**: Relators object to Ms. O'Reilly's testimony to the extent that it would include facts outside of her personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively.

53. **Relators' objections to Gregg Ruppersberger**: Relators object to Mr. Ruppersberger's testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively.

54. **Relators' objections to Debbie Kenworthy**: Relators object to Ms. Kenworthy's testimony to the extent that it would include facts outside of her personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively.

55. **Relators' objections to Mike Driscoll**: Relators object to Mr. Driscoll's testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively.

56. **Relators' objections to Catherine Kaucher**: Relators object to Ms. Kaucher's testimony to the extent that it would include facts outside of her personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively.

57. **Relators' objections to Erin Parsons**: Relators object to Ms. Parson's testimony to the extent that it would include facts outside of her personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively.

58. **Relators' objections to Amit Patel**: Relators object to Mr. Patel's testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively.

59. **Relators' objections to Michael Schiff**: Relators object to Mr. Schiff's testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively.

60. **Relators' objections to Mark Gossett**: Relators object to Mr. Gossett's testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively.

61. **Relators' objections to Glenn Mattes**: Relators object to Mr. Mattes' testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively.

62. **Relators' objections to H. Clifford Lane**: Relators object to Dr. Lane's testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further object that Janssen did not provide a sufficient description of his expected testimony herein.

63. **Relators' objections to B. Kaye Hayes**: Relators object to Ms. Hayes' testimony to the extent that it would include facts outside of her personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further object that Janssen did not provide a sufficient description of her expected testimony herein.

64. **Relators' objections to Cal Cohen**: Relators object to Dr. Cohen's testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further object that Janssen did not provide a sufficient description of his expected testimony herein.

65. **Relators' objections to Juan Bailey**: Relators object to Dr. Bailey's testimony to the extent that it would include facts outside of his personal knowledge, or would offer inadmissible lay opinion testimony. *See* Fed. R. Civ. P. 602 and 701, respectively. Relators further object that Janssen did not provide a sufficient description of his expected testimony herein.

66. **Relators' Note:** Relators object to Janssen taking any trial depositions at this juncture of the case, and presenting any of its witnesses at trial through trial depositions or by remote means. Relators will file a Motion in Limine so that the Court can address this issue in advance of trial. In Relators' view, Janssen should not be permitted to present any witnesses at trial through trial depositions or by remote means. Fact discovery ended in this case over 3 years ago, in March 2019. Janssen has known about the 30 doctors listed on its Witness List since the inception of this case given that they are paid speakers and/or doctors who were subject to Janssen's sales calls (and all or most of them were mentioned in Relators' Complaint or listed in blanket fashion in Janssen's Initial Disclosure Statements). Thus, Janssen had every opportunity to depose these witnesses during the Court-ordered period for fact discovery, but it chose not to do so. There is no Federal Rule of Civil Procedure or Court order that allows Janssen to depose these numerous witnesses at this time, years after fact discovery has ended. In addition, there is nationwide service of process under the False Claims Act, at 31 U.S.C. § 3731(a). This mechanism allows Janssen to present all of its witnesses live at trial. In accordance with Fed. R. Civ. P. 43(a) and case law, trial witnesses should appear live so that the jury can properly assess their demeanor and credibility, and observe Relators' cross examination of them in person.

8. EXPERT WITNESSES (No opposing counsel shall be permitted to question the expert's qualifications unless the basis of an objection is set forth herein).

A. Relators' expert witnesses are:

1. **Virginia Evans. J.D.**, Virginia B. Evans, LLC, 1294 Waldemar Drive, Charlottesville, VA 22903. Ms. Evans will testify in conformity with her Expert Report and deposition testimony. She is expected to testify about facts surrounding, *inter alia,* Janssen's Speaker Program/kickback scheme relating to its prescription HIV drugs Prezista and Intelence; industry standards and government guidance regarding speaker programs; and Compliance issues surrounding Janssen's Speaker Program and off-label marketing.

2. **Aaron Glatt, M.D.**, Hazel Place, Woodmere, New York 11598. Dr. Glatt will testify in conformity with his Expert Report and deposition testimony. He is expected to testify about, *inter alia,* the background of HIV/AIDs and its treatment; the limited approved uses and indications of Prezista and Intelence; how off-label use of Prezista and Intelence can negatively impact patients' health; how off-label marketing impacts doctors' prescriptions behavior; and the lack of value of Janssen's Speaker Program.

3. **James T. O'Reilly. J.D.**, 24 Jewett Drive, Cincinnati, OH 45215. Mr. O'Reilly will testify in conformity with his Expert Report and deposition testimony. He is expected to

testify about, *inter alia,* Janssen's company-wide off-label marketing scheme relating to Prezista and Intelence; the FDA approval process; the approval process for Prezista and Intelence and related marketing materials; federal laws regarding the misbranding or off-label marketing of drugs; Government reimbursements for Prezista and Intelence; and the materiality of Janssen's conduct to the Government's payment decisions.

4. **Kenneth Schafermeyer, Ph.D.**, Pharmacy Administration Consultants, 5628 N. Magnolia Avenue, St. Louis, MO 63139. Dr. Schafermeyer will testify in conformity with his Expert Report and deposition testimony. He is expected to testify about, *inter alia,* regulatory issues, including the Government payment systems under Medicare Part D, the financial impact of Janssen's conduct on Medicare Part D, and CMS' reimbursement rules for prescriptions that are off-label or not medically necessary.

5. **George P. Sillup, Ph.D.**, M.S., Saint Joseph's University, 5600 City Avenue, Philadelphia, PA 19131. Mr. Sillup will testify in conformity with his Expert Report and deposition testimony. He is expected to testify about, *inter alia*, the facts surrounding Janssen's company-wide off-label marketing and Speaker Program/kickback schemes relating to its prescription HIV drugs Prezista and Intelence; the causal relationship between Janssen's off-label marketing and doctors' prescriptions; Janssen's improper use and implementation of its Speaker Program, including for the purpose of disseminating off-label information about the drugs.

6. **Professor Israel Shaked, Ph.D.**, The Michel-Shaked Group, 2 Park Plaza, Suite 500, Boston, MA 02116. Professor Shaked will testify in conformity with his Expert Reports and deposition testimony. He is expected to testify about, *inter alia,* the prescription claims data, the causal relationship between Janssen's off-label marketing and kickback schemes and doctors' prescriptions of Prezista and Intelence, and damages.

7. **Ian M. Dew**, Steck Consulting, LLC, 2021 L Street, NW, Suite 101-304, Washington, DC 20036. Ian Dew will testify in conformity with his Expert Report and deposition testimony. He is expected to testify about, *inter alia*, the claims data as it relates to liability and damages issues.

B. Janssen's objections to the qualifications of Relators' experts are:

1. **Janssen's objections to Virginia Evans, J.D.:** Janssen objects to the extent that Relators' description of Ms. Evans' expected testimony includes topics that the Court has previously excluded. 01/10/2022 Order at 31 [D.E. 294]. Janssen further objects to the extent that Relators' description of Ms. Evans' expected testimony includes testimony that would cover topics outside of her expertise, and/or would be hearsay, irrelevant, or otherwise inadmissible. *See* Fed. R. Evid. 401, 402, 403, 702, & 801 respectively.

2. **Janssen's objections to Aaron Glatt, M.D.:** Janssen objects to the extent that Relators' description of Dr. Glatt's expected testimony includes topics that the Court has previously excluded. 01/10/2022 Order at 27 [D.E. 294]. Janssen further objects to the extent that Relators' description of Dr. Glatt's expected testimony includes testimony that would cover topics outside of his expertise, and/or would be hearsay, irrelevant, or

otherwise inadmissible. *See* Fed. R. Evid. 401, 402, 403, 702, & 801 respectively.

3. **Janssen's objections to James T. O'Reilly, J.D.:** Janssen objects to the extent that Relators' description of Mr. O'Reilly's expected testimony includes topics that the Court has previously excluded. 01/10/2022 Order at 12 [D.E. 294]. Janssen further objects to the extent that Relators' description of Mr. O'Reilly's expected testimony includes testimony that would cover topics outside of his expertise, and/or would be hearsay, irrelevant, or otherwise inadmissible. *See* Fed. R. Evid. 401, 402, 403, 702, & 801 respectively.

4. **Janssen's objections to George P. Sillup, Ph.D.:** Janssen objects to the extent that Relators' description of Mr. Sillup's expected testimony includes testimony that would cover topics outside of his expertise, and/or would be hearsay, irrelevant, or otherwise inadmissible. *See* Fed. R. Evid. 401, 402, 403, 702, & 801 respectively.

5. **Janssen's objections to Israel Shaked, Ph.D.:** Janssen objects to the extent that Relators' description of Professor Shaked's expected testimony includes testimony that would cover topics outside of his expertise, and/or would be hearsay, irrelevant, or otherwise inadmissible. *See* Fed. R. Evid. 401, 402, 403, 702, & 801 respectively.

6. **Janssen's objections to Ian M. Dew:** Janssen objects to the extent that Relators' description of Mr. Dew's expected testimony includes testimony that would cover topics outside of his expertise, and/or would be hearsay, irrelevant, or otherwise inadmissible. *See* Fed. R. Evid. 401, 402, 403, 702, & 801 respectively.

C. Janssen's expert witnesses are:

1. **Babette Edgar.** BluePeak Advisors LLC 2652 FM 407, Suite 215, Bartonville TX 76226. Ms. Edgar is expected to testify regarding Medicare Part D's reimbursement of HIV medications, including Prezista and Intelence. (Live)

2. **Jon Smollen.** 2117 Pine Street, Philadelphia PA 19103. Mr. Smollen is expected to testify regarding pharmaceutical industry standards and government guidance regarding the proper use of speaker programs, and Janssen's efforts to comply with industry standards and government guidance. (Live)

3. **Eric Rosenberg, MD.** 87 Hampton Circle, Hull MA 02045. Dr. Rosenberg is expected to testify regarding HIV care and treatment. (Live)

4. **Anupam (Bapu) Jena, MD.** 70 Temple Road, Wellesley MA 02482. Dr. Jena is expected to testify regarding the factors doctors consider when selecting HIV treatment, as well as the data that would be required, and the methodology that must be used, to reliably evaluate whether Janssen caused doctors to prescribe Prezista or Intelence. Dr. Jena also is expected to testify regarding the data that would be required, and the methodology that must be used, to calculate actual damages in this case if the jury were to find that Janssen violated the False Claims Act. (Live)

D. Relators' objections to the qualifications of Janssen's experts are:

1. **Relators' objections to Babette Edgar**: Relators object to Ms. Edgar's testimony to the extent that it would cover topics outside of her expertise, and/or would be hearsay, irrelevant, or otherwise inadmissible. See Fed. R. Evid. 401, 402, 403, 702, 703, and 801, respectively.
2. **Relators' objections to Jon Smollen**: Relators object to Mr. Smollen's testimony to the extent that it would cover topics outside of his expertise, and/or would be hearsay, irrelevant, or otherwise inadmissible. See Fed. R. Evid. 401, 402, 403, 702, 703, and 801, respectively. Relators further object to Mr. Smollen's testimony to the extent that it is inconsistent with evidence in the record.
3. **Relators' objections to Eric Rosenberg, MD:** Relators object to Dr. Rosenberg's testimony to the extent that it would cover topics outside of his expertise, and/or would be hearsay, irrelevant, or otherwise inadmissible. See Fed. R. Evid. 401, 402, 403, 702, 703, and 801, respectively.
4. **Relators' objections to Anupam (Bapu) Jena, MD**: Relators object to Dr. Jena's testimony to the extent that it would cover topics outside of his expertise, and/or would be hearsay, irrelevant, or otherwise inadmissible. See Fed. R. Evid. 401, 402, 403, 702, 703, and 801, respectively. Relators further object to Dr. Jena's testimony to the extent it is contrary to law.

9. RELATORS' EXHIBITS (Except for exhibits the need for which could not reasonably have been foreseen or which are used solely for impeachment purposes, only the exhibits set forth on the exhibit list attached hereto may be introduced at trial. Any objection to an exhibit, and the reason for said objection, must be set forth below or it shall be deemed waived. All parties hereby agree that it will not be necessary to bring in the custodian of any exhibit as to which no such objection is made).

A. Relators intend to introduce into evidence the exhibits listed on the attached exhibit list (list by number with a description of each):

See attached Exhibit B.

Relators have obtained business record declarations from certain third parties in order to authenticate their documents that appear on Relators' Exhibit Lists. Relators have produced these declarations to Janssen.

B. Janssen objects to the introduction of Relators' exhibits (set forth number of an exhibit and grounds for objection):

See Exhibit C for Janssen's objections to Relators' exhibits.

10. JANSSEN'S EXHIBITS

A. Janssen intends to introduce into evidence the exhibits listed on the attached exhibit list (list by number with a description of each):

See Exhibit D for Janssen's exhibit list.

B. Relators object to the introduction of Janssen's exhibits (set forth number of exhibit and grounds for objection):

See Exhibit E for Relators' objections to Janssen's exhibits.

11. RELATORS' LEGAL ISSUES

False, Misleading, Misbranding and Off-Label Marketing Claims

Whether Janssen is liable for violations of Sections 3729(a)(1)(A) and (B) of the federal False Claims Act, 31 U.S.C. 3729, *et seq.* ("FCA") and the analogous provisions of the Plaintiff States' false claims acts ("Plaintiff States' Analogs")[6] as a result of Janssen's false, misleading, misbranding, and/or off-label promotion of two of its HIV/AIDS treatment drugs, Prezista and Intelence.

Specifically, with regard to a violation of Section 3729(a)(1)(A) of the FCA and the Plaintiff States' Analogs, whether Janssen knowingly presented, or caused to be presented, false or fraudulent claims for payment to the United States and the Plaintiff States, as a result of its false, misleading, and/or off-label promotion of Prezista and Intelence to doctors, including whether:

- Janssen presented or caused to be presented a claim for payment to the United States and Plaintiff States;

- The claim was false or fraudulent because it was ineligible for reimbursement as it was for an off-label use or for a medically unreasonable or unnecessary use; was misbranded in violation of the Food, Drug and Cosmetics Act, 21 U.S.C. §§ 355(a) & (d); and/or contained false express certifications of compliance with the law.

- The falsity was material to a decision to pay the claim; and

[6] The "Plaintiff States" are California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, and Washington. The Plaintiff States' Analogs include all of the Plaintiff States (except for Texas which is discussed separately below because the elements of proof under the Texas law are slightly different) and are set forth in the Second Amended Complaint Counts III, V, VII, IX, XI, XIII, XV, XVII, XIX, XXI, XXIII, XXV, XXVII, XXIX, XXXI, XXXIII, XXXV, XXXVII, XXXIX, XLI, XLIII, XLV, XLVII, LI, LIII, LV.

- Janssen had sufficient knowledge that the claim was false or fraudulent.

Specifically, with regard to a violation of Section 3729(a)(1)(B) of the FCA and the Plaintiff States' analogs, whether Janssen knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims to the United States and the Plaintiff States, as a result of its false, misleading, and/or off-label promotion of Prezista and Intelence to doctors, including whether:

- Janssen made or used, or caused to be made or used, a record or statement material to a false or fraudulent claim;

- The record or statement was false because it was for an off-label use or for a medically unreasonable or unnecessary use; was misbranded in violation of the Food, Drug and Cosmetics Act, 21 U.S.C. §§ 355(a) & (d); and/or contained false express certifications of compliance with the law.

- The falsity was material to a decision to pay the claim; and

- Janssen had sufficient knowledge that the record or statement was false.

Kickback Claims

Whether Defendant is liable for violations of Section 3729(a)(1)(A) of the federal FCA and the Plaintiff States' Analogs[7] for knowingly presenting, or causing to be presented, false or fraudulent claims for payment to the United States and Plaintiff States, as a result of knowingly paying kickbacks to doctors for its Speaker Program and other services with at least the one purpose of inducing them to prescribe Prezista and Intelence, or to reward them for doing so.

Specifically, with regard to a violation of Section 3729(a)(1)(A) of the FCA and the Plaintiff States' analogs, whether Janssen knowingly presented, or caused to be presented, false or fraudulent claims for payment to the United States and Plaintiff States, including whether:

- Janssen presented or caused to be presented a claim for payment to the United States and Plaintiff States;

- The claim was false or fraudulent because it violated the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), including whether:

    - Janssen offered or paid any remuneration;

    - The offer or payment of remuneration was made with at least one purpose to

[7] *See* Second Amended Complaint Counts II, IV, VI, VIII, X, XII, XIV, XVI, XVIII, XX, XXII, XXIV, XXVI, XXVIII, XXX, XXXII, XXXIV, XXXVI, XXXVIII, XL, XLII, XLIV, XLVI, XLVIII, LII, LIV, LVI.

induce or reward Prezista and Intelence prescriptions which may be paid in whole or part by Medicare, Medicaid and/or ADAP; and

- Janssen did so knowingly.

- The falsity (*i.e.*, the violation of the AKS) was material to a decision to pay the claim; and

- Janssen had sufficient knowledge that the claim was false or fraudulent.

Claims under Texas Law[8]

Whether Janssen knowingly caused false statements or misrepresentations of material facts to be made to permit payment under the Texas Medicaid program that were not authorized.

Whether Janssen knowingly concealed or failed to disclose information to permit payment under the Texas Medicaid program that were not authorized.

Whether Janssen knowingly caused claims to be presented to the Texas Medicaid program that contained statements or representations that Janssen knew or should have known to be false.

Whether Janssen knowingly (meaning acted with knowledge or conscious indifference to the truth of the matter) offered to pay or give, or did pay or give, doctors gifts of money, a donation, or other items of value for the purpose of influencing the writing of prescriptions of Prezista and Intelence that would ultimately be paid for, in whole or in part, by the Texas Medicaid program.

Damages and Other Relief

If Defendant is found liable for violation(s) of the federal FCA and/or the Plaintiff States' Analogs and/or Texas law, what is the total amount of damages the United States and Plaintiff States are entitled to, including the amount of trebled damages, the total amount of civil penalties, and the amount of reasonable attorney's fees, expenses, and costs.

12. JANSSEN'S LEGAL ISSUES

Relators allege Janssen violated the False Claims Act through its promotional messages ("Promotional Claims") and speaker programs ("Speaker Claims") related to Prezista and Intelence. Janssen has not violated the federal False Claims Act, or any analogous state statute,[9] which, contrary to Relators' position, is as follows.

[8] *See* Second Amended Complaint Counts XLIX and L.

[9] For their state law claims, Relators have not produced any evidence of what constitutes a "false" claim under each state's respective law, and what factors, if any, are material to each state's decision to pay claims submitted for reimbursement of HIV medication prescriptions. As a result, Janssen has not addressed any legal issues related

Promotional Claims

For the Promotional Claims, Relators allege Janssen violated the False Claims Act when it improperly promoted HIV medications Prezista and Intelence, causing doctors to prescribe these medications to government-insured HIV patients, which then caused the Government to pay for Prezista and Intelence prescriptions that it would not have paid for otherwise.

To show Janssen violated the False Claims Act for the Promotional Claims, Relators must prove by a preponderance of the evidence the following:

First, Janssen caused a doctor to write a Prezista or Intelence prescription that was submitted to a Government health insurance program as a claim for reimbursement. This means that Relators must prove that Janssen's promotion was a substantial factor in causing a doctor to write a Prezista or Intelence prescription that was submitted to a Government health insurance program as a claim for reimbursement.

Second, the claim for reimbursement was false. Government health insurance programs provide coverage for prescription medications, but are allowed (and under some circumstances do) place limitations on what the insurance programs will and will not cover. Relators allege that claims for payment of Prezista and Intelence prescriptions were not eligible for coverage under Government health insurance programs because they were either not medically reasonable and necessary[10] or were not for a use approved by the FDA.

Third, the falsity was material to the Government health insurance program's decision to pay the claim.

Fourth, Janssen knew that the claim was false.

It is, however, legal for pharmaceutical companies to provide truthful, non-misleading information that is not included in a medication's label. That is, it is lawful to provide information that is about off-label studies or uses so long as it is truthful and not misleading. *See United States v. Caronia*, 703 F.3d 149, 168-69 (2d Cir. 2012).

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to those alleged claims.

[10] It is Janssen's position that Medicare does not require medications covered by Medicare Part D (the Medicare part at issue in this case) be "reasonable and necessary" to be eligible for reimbursement. Medicare Part D plan sponsors—that is, the health plans, insurers and employers that administer Medicare Part D—*may* exclude certain medications from coverage for a variety of reasons, including because the Part D plan sponsor has determined that the medication is not reasonable and necessary. No Part D plan sponsor in this case has made such a determination. Nevertheless, in denying Janssen's motion to dismiss Relators' complaint in this case, this Court found that Prezista prescriptions may be ineligible for reimbursement if they not reasonable and necessary. Janssen respectfully reserves its rights to raise this legal argument in the future, including on appeal.

Speaker Claims

For the Speaker Claims, Relators allege that Janssen improperly paid doctors to work as consultants to educate other doctors about Prezista and Intelence, and that Janssen violated the federal Anti-Kickback Statute and False Claims Act because it intended these payments to induce the doctors they paid to prescribe Prezista and Intelence or reward them for doing so.

To show Janssen violated the False Claims Act for the Speaker Claims, Relators must first prove by a preponderance of the evidence that Janssen violated the Anti-Kickback Statute. This means Relators must prove by a preponderance of the evidence the following:

First, Janssen paid money—including any kickback or bribe—to doctors who were speakers at its speaker programs.

Second, one purpose of the payments was to induce the doctors who were speakers to prescribe Prezista and Intelence.

Third, Government health insurance programs paid for Prezista or Intelence prescriptions resulting from such unlawful payments.

Fourth, Janssen acted knowingly and willfully with respect to all of these elements. To act "knowingly" means that Janssen was conscious and aware of the nature of its actions and of the surrounding facts and circumstances. To act "willfully" means that Janssen knew its conduct was unlawful and intended to do something that the law forbids.

Because a violation of the Anti-Kickback Statute requires proof that Janssen acted knowingly and willfully, if Janssen acted in good faith, that is a complete defense to the alleged violation. Good faith is a defense because it is inconsistent with the requirement of the Anti-Kickback Statute that Janssen acted knowingly and willfully. A person acts in good faith when he or she has an honestly held belief, opinion, or understanding about the existence of a fact or in the truth of statements, even though the belief, opinion, or understanding turns out to be inaccurate or incorrect. Therefore, in this case, if Janssen made an honest mistake or had an honest misunderstanding about the existence of a fact or in the truth of statements then it did not act knowingly and willfully.

For purposes of the False Claims Act, a claim submitted for reimbursement to a Government health insurance program in violation of the Anti-Kickback Statute is a false claim. If Relators prove that Janssen violated the Anti-Kickback Statute, to find Janssen liable under the False Claims Act for the Speaker Claims, Relators must then prove by a preponderance of the evidence that the falsity was material to the Government's decision to pay the claim.

Damages

If Relators are able to prove by a preponderance of the evidence that Janssen violated the False Claims Act for the Promotional Claims and/or the Speaker Claims, to award any damages, Relators must prove by a preponderance of the evidence that the Government suffered an actual monetary loss. The purpose of the False Claims Act is to make the United States whole. Damages, if any, must be fair compensation for the Government's losses, no more and no less. Damages are not allowed as a punishment and cannot be imposed or increased to penalize Janssen. In this case, the measure of damages is the difference between the amount of money the Government paid for Prezista and Intelence and the value of what the Government actually received. *See, e.g., United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1279 (D.C. Cir. 2010); *United States ex rel. Wall v. Circle C Constr., LLC*, 813 F.3d 616, 617 (6th Cir. 2016).

13. **CHOICE OF LAW:** (If there is any issue as to what state's law is applicable to any count of the complaint, set forth the choice of law question. This issue shall be separately briefed in accordance with an order to be entered herewith).

N/A

14. **MISCELLANEOUS**

Joint

Pursuant to this Court's Letter Order dated June 14, 2021 (Dkt 259), Janssen produced documents from the custodial files of Amit Patel, Kimberlee Saladana, and Michael Driscoll. The parties are working together to schedule the depositions of these witnesses. Both parties have supplemented their Exhibit Lists with documents produced from these witnesses' files.

Relators

Relators' Position on Janssen's Contemplated Motions

Relators intend to oppose every one of Janssen's Contemplated Motions at the appropriate time, but we hereby address a few of them below.

With regard to Janssen's proposed motion in limine to preclude Relators and certain lay witnesses from testifying based on lack of personal knowledge (No. 1), Relators intend to contest this motion as not a true or appropriate motion in limine that can be ruled upon in advance of trial. Whether a witness has personal knowledge of a particular fact can only be determined once the witness testifies and speaks about the bases of his/her knowledge. Janssen can make its objections at trial.

With regard to Janssen's proposed motion to exclude any evidence or argument referring

to Janssen's promotion of Prezista's lipid profile, Prezista prescriptions written for patients with lipid conditions, or claims submitted for Prezista prescriptions written for patients with lipid conditions as "off-label" (No. 4), Relators intend to contest this motion as totally inappropriate as a motion in limine and more akin to a motion to dismiss. It improperly attempts to prevent Relators from presenting evidence and argument as to their Prezista lipid claims which the Court has already upheld in denying summary judgment.

With regard to Janssen's proposed motion to exclude any evidence referring to Prezista or Intelence prescriptions as "misbranded" or otherwise "illegal" (No. 5), Relators will contest this motion as being contrary to the law, as Relators allege that the prescriptions were in fact misbranded and illegal under the law.

With regard to Janssen's proposed motion to exclude any evidence or argument referencing Anthony Dolisi's assertion of the Fifth Amendment (No. 8), Relators will oppose this motion based on case law decided by the Third Circuit and other courts holding that evidence of depositions of non-party witnesses who exercised their Fifth Amendment privileges is admissible, and juries may be permitted to draw adverse inferences therefrom. Anthony Dolisi was Relators' direct supervisor. Relators both testified that he directed them to promote Prezista and Intelence for off label purposes. When the government deposed Mr Dolisi about these issues, he refused to answer almost every question based upon the Fifth Amendment. The jury in this case should be aware of these relevant facts, and should be permitted to draw adverse inferences related thereto.

Relators' Counsels' Attorney Work Product Memorandum

Relating to Janssen's request for Relators' counsels' attorney work product, in connection with Relators' expert Professor James O'Reilly, discussed below by Janssen, Relators state as follows: The materials that Janssen now seek are classic attorney work product as they reflect the mental impressions, opinions, and analyses of Relators' counsel regarding the facts, evidence, legal claims, and damages in this case. The materials themselves are designated as "Confidential Attorney Work Product", "Protected From Disclosure Under Joint Stipulation". Janssen has no right to obtain this work product, and the fact that these materials were provided to Professor O'Reilly does not change this fact. Indeed, under the parties' agreed-upon and Court-ordered Stipulation dated May 22, 2019 (ECF 153), communications and memos, including work product, exchanged between counsel and experts are protected against disclosure unless the expert relies on the information as a basis for his opinions. (*Id*., ¶¶ 3-4). That exception does not apply here. None of Relators' experts (including Prof. O'Reilly) mentioned these memos in their written expert reports, they did not list these memo in their Materials Relied Upon, and they did not offer any testimony whatsoever that they ever relied upon these memos when forming their opinions. Janssen cannot produce any evidence to the contrary, as none exists. Thus, in accordance with the Stipulation that Janssen agreed to, these work product memos are protected against disclosure. Finally, Janssen raised this issue with Relators over two and a half years ago, in March 2020, after Prof O'Reilly had been deposed. Relators responded in writing on March 10, 2020. Janssen then dropped the issue entirely. There is

no Federal Rule of Civil Procedure or Court Order that allows Janssen to now make a motion to compel regarding these materials several years after fact and expert discovery have ended. Its request is substantively and procedurally improper, and it should be denied. It has no valid basis to obtain Relators' counsels' attorney work product and should be precluded from doing so.

Relators' Position on Janssen's Contested Facts Regarding Damages

Relators also note that Janssen has previously filed a Daubert motion against Prof. Shaked raising many of the same arguments as asserted herein in Janssen's Section B above setting forth contested facts regarding damages, and the Court denied their motion in its entirety. (Dkt. 294).

Janssen

Janssen's Positions on Witness Issues

Judge Quraishi will permit either in person or remote testimony of physicians. The parties are directed to confer on this issue. If the parties cannot reach an agreement, they may submit a joint letter, no longer than five pages.

- During the June 21 and September 6, 2022 final pretrial conferences, the Court stated that it would seek guidance from Judge Castner on her preference for the presentation of testimony from doctors and other witnesses who do not reside in the District and who may be unavailable to travel to Trenton, New Jersey for the trial. Janssen therefore awaits further guidance from the Court before taking a position on whether remote testimony or trial depositions are appropriate or necessary.

- As described in Section 6(C)(19) above, Relators are seeking trial testimony that is not allowed under the Federal Rules. Relators' counsel made the strategic decision to notice Rule 30(b)(6) depositions. Relators' counsel then made the strategic decision to withdraw its notice and to not seek Rule 30(b)(6) depositions. Now, with trial imminent, Relators are improperly seeking a Rule 30(b)(6) deposition witness as a trial witness to testify on "substantive issues." At trial, "a corporate representative may not testify to matters outside his own personal knowledge 'to the extent that information [is] hearsay not falling within one of the authorized exceptions.'" *Union Pump Co. v. Centrifugal Tech., Inc.*, 404 F. App'x 899, 907-08 (5th Cir. 2010); *see also TIG Ins. Co. v. Tyco Int'l Ltd.*, 919 F. Supp. 2d 439, 454 (M.D. Pa. 2013) ("Although Rule 30(b)(6) allows a corporate designee to testify to matters within the corporation's knowledge during deposition, at trial the designee 'may not testify to matters outside his own knowledge to the extent that information is hearsay not falling within one of the authorized exceptions.'").

  Additionally, a Janssen corporate representative is not necessary to "authenticate Janssen documents." Janssen is not objecting to the authenticity of the documents produced from its files, except for certain documents that Relator Christine Brancaccio saved to her Janssen files and that do not appear to be authentic business records.

- Relators' proffered regulatory expert, Professor James O'Reilly, testified at his deposition that Relators' counsel provided him with "materials" that were not produced

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in this case and that he read and considered when evaluating whether to serve as an expert for Relators. Mr. O'Reilly testified that the materials included (among other things) general background on the case. Mr. O'Reilly decided to serve as an expert witness based on the information contained in these materials.

In March 2020, Janssen requested a copy of the materials Mr. O'Reilly described, and Relators' counsel responded that it is not discoverable under the Stipulation pertaining to expert witnesses (See ECF 153) because Mr. O'Reilly did not rely on the materials to render his opinion.

Based on Mr. O'Reilly's testimony, however, the materials were the factual prerequisites to his retention, and he considered and relied on the information in the materials when he agreed to testify on Relators' behalf. Janssen is therefore entitled to them.

- Relators and certain of their witnesses raised common interest and other privileges in response to subpoenas, requests for documents, and at depositions. Janssen does not believe that all of these privilege assertions were appropriate and intends to continue to try to resolve these issues without court intervention.

Janssen's Positions on Relators' Contemplated Motions

- Janssen intends to oppose every one of Relators' Contemplated Motions at the appropriate time, but would like to make the following points.

- Relators' contemplated motion in limine No. 11 is a motion to challenge or exclude Dr. Jena's expert testimony. The parties jointly agreed that all motions to challenge or exclude expert testimony must be filed contemporaneously with any motions for summary judgment. The Court reviewed and entered the parties' draft joint stipulated scheduling order, setting an October 14, 2020 deadline. *See* 9/10/20 Order at 1 [D.E. 178]. In accordance with the Court's deadline, Relators filed a motion to exclude Dr. Jena's opinions on causation and damages, arguing (among other things) that Dr. Jena's opinions were contrary to law. *See Relators' Mem. Of Law in Supp. Of Mot. to Exclude Certain Ops. Of Janssen's Expert Dr. Anupam Jena* at 4 [D.E. 277]. The Court denied Relators' motion, finding that "to the extent that Relators believe that Jena applies the incorrect legal test with respect to causation, that issue can be adequately tested by cross-examination" and that "[a]lthough Relators may disagree, Jena's opinions are informed by Janssen's version of events, which is not a basis to exclude an otherwise reliable and relevant opinion." *See* 1/10/2022 Mem. Op. at 41, 44 – 45 [D.E. 294]. Relators are now improperly seeking a second bite at the apple. They should not be permitted to do so.

Janssen's Positions on Trial Logistics

- Relators filed the original complaint under seal in this matter nearly ten years ago. The parties have been actively litigating the matter for almost six years. Given the length of

time this matter has been pending, Janssen respectfully requests that the Court schedule this case for trial at the Court's earliest convenience.

- Janssen requests the use of a case-specific questionnaire for potential jurors and will propose a questionnaire for the parties to agree upon prior to trial.

15. JURY TRIALS - Not later than _____.

Judge Quraishi will set a trial date after the Motions in limine are decided.

Unless otherwise ordered:

A. Each side shall submit to the Judge and to opposing counsel a trial brief or memorandum in accordance with Local Civil Rule 7.2B, with citations to authorities and arguments in support of its position on all disputed issues of law. In the event a brief shall not be filed, the delinquent party's complaint or defense may be stricken. Trial briefs are due ~~15~~ 30 days before trial. Opposition due 15 days before trial

B. Counsel for each party shall submit to the Judge, with a copy to opposing counsel, written requests for instructions to the jury. Supplemental requests for instructions may be submitted at any time prior to argument to the jury. All requests for instructions shall be plainly marked with the name and number of the case, shall contain citations of supporting authorities, if any, and shall designate the party submitting same. In the case of multiple requests by a party, these shall be numbered in sequence and each request shall be on a separate sheet of paper. Jury instructions are due 15 days before trial.

C. Joint proposed verdict form/special interrogatories are to be submitted to the trial judge 15 days before trial.

D. Proposed voir dire are to be submitted to the trial judge 15 days before trial.

E. ~~Motions in limine are due 45 days before trial. Oppositions are due 30 days before trial.~~ Motions in limine are to be filed by 11/23/22; opposition due 12/5/22; reply due 12/12/22; returnable 12/19/22

F. Deposition designations are due 45 days before trial. Counter designations and objections are due 15 days before trial.

G. Notice of any evidence the parties intend to offer in their case in chief under Fed. R. Evid. 404 is due 45 days before trial. Oppositions are due 30 days before trial.

16. NON-JURY TRIALS - Not later than _____.

A. Each side shall submit to the Judge and opposing counsel a trial brief or memorandum in accordance with Local Civil Rule 7.2B with citation to authorities and arguments in support of its position on all disputed issues of law. In the event a brief shall not be filed, the delinquent party's complaint or defense may be stricken.

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B. Each side shall submit to the Judge and other counsel proposed written findings of fact and conclusions of law. There is reserved to counsel the right to submit additional proposed findings of fact and conclusions of law during the course of the trial on those matters that cannot reasonably be anticipated.

17. TRIAL COUNSEL (List the names of trial counsel for all parties). Trial counsel for Relators are: Joshua Russ, Andrew Wirmani, Pete Marketos, and Allison Cook of Reese Marketos LLP, and Sherrie Savett, Joy Clairmont, Michael Fantini, and William Ellerbe of Berger Montague PC.

Trial counsel for Janssen are Abigail A. Hazlett, Brian M. Nichilo, and Michael A. Schwartz of Troutman Pepper Hamilton Sanders LLP and Allison Brown and Geoffrey M. Wyatt of Skadden, Arps, Slate, Meagher & Flom LLP.

18. BIFURCATION (Where appropriate, the issues relating to liability shall be severed and tried to verdict. Thereafter, all issues relating to damages will be tried).

The parties agree that the issues of liability and damages SHALL NOT be tried separately.

19. ESTIMATED LENGTH OF TRIAL

The parties estimate there will need to be twenty-five days of trial.

AMENDMENTS TO THIS PRETRIAL ORDER WILL NOT BE PERMITTED UNLESS THE COURT DETERMINES THAT MANIFEST INJUSTICE WOULD RESULT IF THE AMENDMENT IS DISALLOWED.

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DATED: November 2, 2022

UNITED STATES MAGISTRATE JUDGE

(RELATORS' EXHIBITS A, B, AND E TO FOLLOW)
(JANSSEN'S EXHIBITS C AND D TO FOLLOW)